Dexcom G4® PLATINUM Pediatric

CONTINUOUS GLUCOSE MONITORING SYSTEM

Receiver with *Share*™

USER'S GUIDE

USER'S GUIDE
DEXCOM G4® PLATINUM (PEDIATRIC) CONTINUOUS GLUCOSE MONITORING SYSTEM RECEIVER WITH *Share*™

IMPORTANT CONTACTS AND NUMBERS

Dexcom® Website:	www.dexcom.com
Your Transmitter ID:	
Your Receiver ID:	
Your Healthcare Professional:	
Nearest Hospital:	

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DEXCOM G4 PLATINUM (PEDIATRIC) CONTINUOUS GLUCOSE MONITORING SYSTEM

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GLOSSARY

Alternative Site BG Testing	This is when you take a blood glucose value on your meter using a blood sample from an area on your body other than your fingertip. Do not use alternative site testing to calibrate your receiver.
Applicator	A disposable piece that comes attached to the sensor pod and inserts the sensor under the skin. There is a needle inside the applicator that you remove after you insert the sensor.
BG Meter	Blood glucose meter. A device used to measure how much glucose is in the blood. You can use any commercially available meter for testing your blood glucose.
BG Value	Blood glucose value. The measurement of glucose in the blood. A blood glucose value taken with your commercially available blood glucose meter.
***Bluetooth*®**	*Bluetooth* wireless technology allows devices to wirelessly communicate with each other. In this case, communication between the receiver and your iPhone®/iPod touch® device.
Calibration	When you enter blood glucose values from a blood glucose meter into the receiver. Calibrations are needed for your receiver to show continuous sensor glucose readings and trend information. (Do not use alternative site testing for calibration).
CGM	Continuous Glucose Monitoring.
Commercially Available	Product that may be sold in the United States.
Default	A setting that is selected automatically, unless you choose another option.

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GLOSSARY (continued from page before)

Dexcom G4 PLATINUM (Pediatric) System	The sensor, transmitter, and receiver.
Dexcom Share™ System	Secondary notification system to the Dexcom G4 PLATINUM System. For more information, please refer to the Dexcom Share User Manual.
Glucose Data Gaps	Different symbols show on the trend graph instead of a sensor glucose reading to let you know that the receiver cannot provide a reading.
Glucose Trends	Trends let you see the pattern of your glucose levels. The trend graph shows where your glucose levels have been during the time shown on the screen and where your glucose levels are now.
Hypoglycemia	Low blood glucose. Same as "low." The default low alert in your receiver is set to 80 mg/dL. Consult your healthcare professional to determine the appropriate hypoglycemic setting for you.
Hyperglycemia	High blood glucose. Same as "high." The default high alert in your receiver is set to 200 mg/dL. Consult your healthcare professional to determine the appropriate hyperglycemic setting for you.
HypoRepeat	Optional receiver alert setting that keeps repeating the fixed low alarm every 5 seconds until your sensor glucose reading rises above 55 mg/dL or you confirm it. This profile can be helpful if you want extra awareness for severe lows.
mg/dL	Milligrams per deciliter. The standard unit of measure for sensor glucose readings in the United States.

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GLOSSARY (continued from page before)

Obstruction	Something that blocks the wireless path between the transmitter and receiver. There are many types of things that could come between the transmitter and receiver, and Dexcom could not test them all. “Without obstruction” means that we have not tested whether items blocking the transmitter or receiver could affect the transmission range.
Profiles	Sound pattern and volume level settings for your alerts.
Range	The distance between the receiver and transmitter. Keep the two devices within 20 feet of each other without obstruction to get glucose information on your receiver.
Re-Alert	A re-alert happens after the first alert is not confirmed.
Receiver	The small device that collects your glucose information from the sensor/transmitter. Your results show on the receiver screen as a sensor glucose reading (mg/dL) and as a trend.
Rise and Fall (Rate of Change) Alerts	Alerts based on how fast and how much your glucose levels rise/fall.
RF	Radio-frequency transmission used to send glucose information from the transmitter to the receiver.
Safety Lock	The safety lock keeps the needle inside the applicator before you are ready to insert the sensor. It also helps you snap the transmitter out of the sensor pod after your sensor session ends.

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GLOSSARY (continued from page before)

Sensor	The Dexcom G4 PLATINUM (Pediatric) System part that includes an applicator and wire. The applicator inserts the wire under your skin, and the wire measures glucose levels in your tissue fluid.
Sensor Pod	The small plastic base of the sensor attached to your skin that holds the transmitter in place.
Snoozing	The option to delay your alert for a set amount of time. A snooze time can be set for high and low glucose re-alerts.
Startup Period	The 2-hour period after you tell the receiver you inserted a new sensor. Sensor glucose readings are not provided during this time.
System Reading	A sensor glucose reading shown on your receiver. This reading is in mg/dL units and is updated every 5 minutes.
Transmitter	The Dexcom G4 PLATINUM (Pediatric) System part that snaps into the sensor pod and wirelessly sends glucose information to your receiver.
Transmitter ID	A series of numbers and/or letters that you enter into your receiver to let it communicate with the transmitter.
Transmitter Latch	The small, disposable piece that snaps the transmitter into the sensor pod. It is removed after the transmitter is snapped in.
Trend (Rate of Change) Arrows	Arrows on trend graphs that show how fast your glucose levels are changing. There are 7 different arrows that show when your glucose speed and direction change.

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chapter one

DEXCOM G4 PLATINUM (PEDIATRIC) CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM DESCRIPTION

1

CHAPTER 1: DEXCOM G4® PLATINUM (PEDIATRIC) CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM DESCRIPTION

Dexcom G4 PLATINUM (Pediatric) Receiver with Share

Dexcom G4 PLATINUM Sensor

Dexcom G4 PLATINUM Transmitter

1.1 SYSTEM CONTENTS:

- sensor
- transmitter
- receiver
- receiver USB charging/download cable
- AC power adapter - MT21255
- receiver case
- user's guide
- quick start guide
- training checklist
- tutorial disc
- Dexcom STUDIO™ software (available for download online at www.dexcom.com)

Sensors are sold separately. Commercially distributed blood glucose (BG) meter required for use.

PRECAUTION

The Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver are not compatible with the SEVEN®/SEVEN® PLUS Transmitter and Receiver. Different generations will not connect with each other and will not work. Also, make sure to use the correct version of Dexcom STUDIO with your system.

1.2 INTRODUCTION

When you use the system, you will see continuous sensor glucose readings updated every 5 minutes for up to 7 days. These readings will help you notice trends and patterns in your glucose levels.

The system includes the Dexcom G4 PLATINUM Sensor, the Dexcom G4 PLATINUM Transmitter, and the Dexcom G4 PLATINUM (Pediatric) Receiver with Share. The sensor is a disposable unit that you insert under your skin to continuously monitor your glucose levels for up to 7 days. The transmitter is a reusable device that wirelessly sends your sensor's glucose information to your receiver. The receiver is a hand-held device that receives and displays your glucose information.

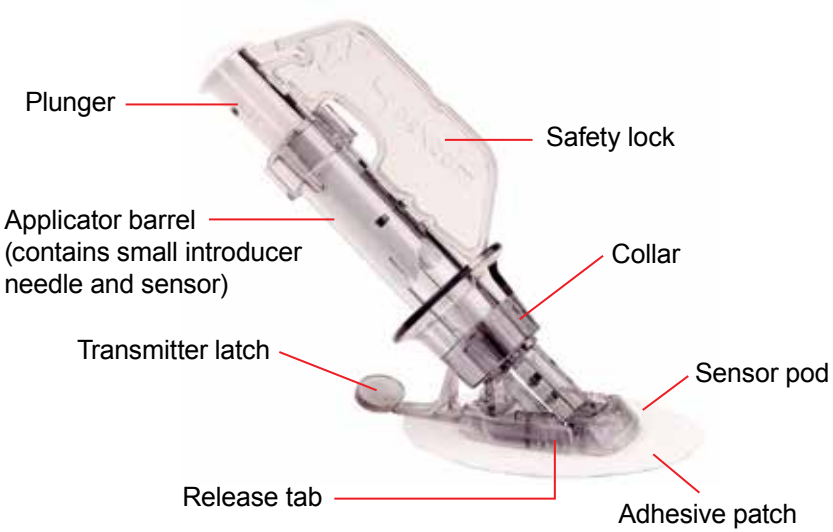
Please read this user's guide closely. It describes how to use your system.

In addition, Dexcom® has a self-guided training tutorial for the Dexcom G4 PLATINUM (Pediatric) CGM System. Some people have found this to be an effective method of product training. Please review the tutorial on the disc and discuss with your healthcare professional to decide if the Dexcom G4 PLATINUM (Pediatric) System Tutorial is a good training option for you. The tutorial disc can only be used with your computer and cannot be used in DVD players. The tutorial is also found on the Dexcom website – www.dexcom.com.

1.3 SENSOR OVERVIEW

The sensor is the piece that comes in a sterile, sealed sensor pouch. The sensor is made up of an applicator, a sensor pod, and a sensor wire. You remove the applicator after insertion. The sensor pod stays on your skin for the entire sensor session, up to 7 days. The pod is made of plastic and an adhesive patch. The sensor wire is thin and flexible, and inserts just under your skin. It is attached to the sensor pod, and is made of silver and platinum metal with polymer membranes. You discard the sensor at the end of the session.

See Chapter 14 for Product Specifications.



1.4 TRANSMITTER OVERVIEW

The transmitter is the gray, plastic “chip” that snaps into your sensor pod. The 9438-01 transmitter (including sensor pod) is 1.5 inches long, 0.9 inches wide and 0.5 inches thick. The 9438-05 transmitter (including sensor pod) is 1.5 inches long, 0.9 inches wide and 0.4 inches thick. Once snapped into the sensor pod, the transmitter wirelessly sends your glucose information to the receiver. The transmitter and sensor are water resistant when properly connected. Do not throw away your transmitter. It is reusable.

The transmission range from the transmitter to the receiver is up to 20 feet without obstruction. Wireless communication does not work well through water, so the range is much less if you are in a pool, bathtub or water bed.

The transmitter battery will last at least 6 months. Once you see the transmitter low battery screen, replace the transmitter as soon as possible. Your transmitter battery may drain as quickly as one week after this alert appears.

See Chapter 14 for Product Specifications.

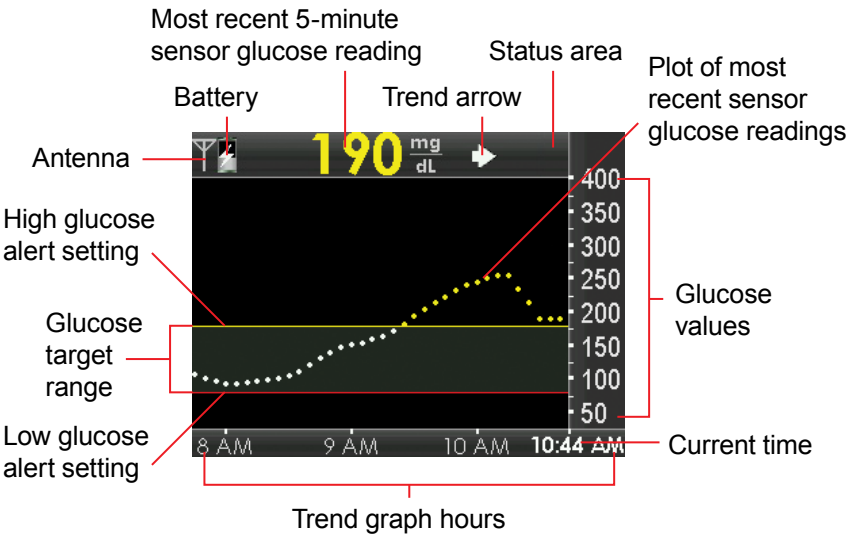
Transmitter

Transmitter Low Battery screen

1.5 RECEIVER OVERVIEW

The receiver is the small hand-held device that looks like a cell phone. It is about 4 inches long, 1.8 inches wide and 0.5 inches thick. It shows your sensor glucose readings, trend graph, direction and rate of change arrow.

Do not spill fluids on the receiver or drop the receiver into fluids. Keep the micro USB port door closed to help prevent fluid and dust from getting inside the receiver.



EXAMPLE: 3-Hour Trend Graph Screen

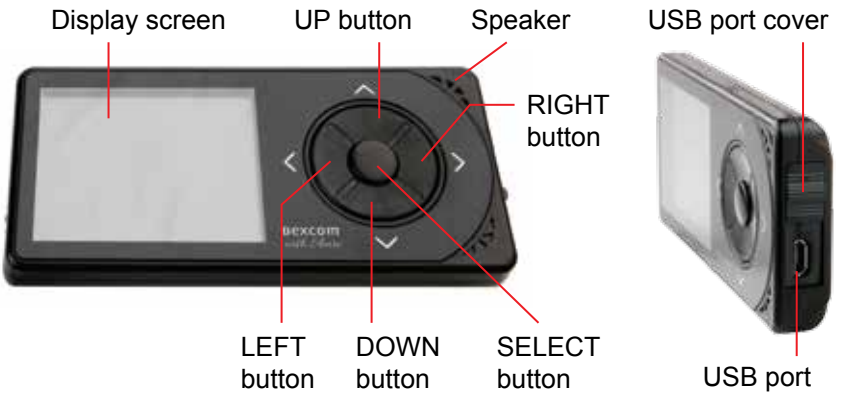
The trend graph screen on your receiver shows your sensor glucose readings, trend graph, direction and rate of change arrow

There are five receiver buttons to move you through the screens. The trend graph screens show sensor glucose readings, trend graphs and trend arrows. The receiver menu screens let you change your receiver settings.

Your receiver and transmitter wirelessly pair together to communicate securely and only with each other.

You will need a commercially available blood glucose meter to use with your system.

See Section 14 for Product Specifications.



Receiver buttons:

- Press the **UP** and **DOWN** buttons to scroll through trend graph screens, highlight menu items, or set values.
- Press the **SELECT** button to turn the receiver on or select the highlighted option.
- Press the **LEFT** button to go back to the last item or screen.
- Press the **RIGHT** button to highlight the next item.

1.6 SHARE OVERVIEW

Dexcom Share™ remote monitoring system lets one person, the Sharer, transfer Dexcom G4 PLATINUM Continuous Glucose Monitoring information to another person, the Follower.

Learn more about Dexcom Share by reading the Dexcom Share User Manual.

chapter two

INDICATIONS FOR USE AND SAFETY STATEMENT

2

CHAPTER 2: INDICATIONS FOR USE AND SAFETY STATEMENT

2.1 INDICATIONS FOR USE

The Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring System is a glucose monitoring device indicated for detecting trends and tracking patterns in persons ages 2 to 17 years with diabetes. The system is intended for single patient use and requires a prescription.

The Dexcom G4 PLATINUM (Pediatric) System is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices.

The Dexcom G4 PLATINUM (Pediatric) System aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the Dexcom G4 PLATINUM (Pediatric) System results should be based on the trends and patterns seen with several sequential readings over time.

2.2 IMPORTANT USER INFORMATION

Please review your product instructions before using your continuous glucose monitoring system. Indications, contraindications, warnings, precautions, cautions, and other important user information can be found in your product instructions. Discuss with your healthcare professional how you should use your sensor trend information to help manage your diabetes. Your product instructions contain important information on troubleshooting your system and on the performance characteristics of the device.

2.3 CONTRAINDICATIONS

- Remove the Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. The device is MR Unsafe. Do not bring any portion of the device into the MR environment. The Dexcom G4 PLATINUM (Pediatric) System has not been tested during MRI or CT scans or with diathermy treatment. The magnetic fields and heat could damage the device so that it might not display sensor glucose readings or provide alerts, and you might miss a low or high blood glucose value.
- Taking medications with acetaminophen (such as Tylenol®) while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.

2.4 WARNINGS

- Do not use the Dexcom G4 PLATINUM (Pediatric) CGM System until you have thoroughly reviewed the training materials. Incorrect use might lead you to misunderstand the CGM information or affect system accuracy. This could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Do not use the Dexcom G4 PLATINUM (Pediatric) System for treatment decisions, such as how much insulin you should take. The Dexcom G4 PLATINUM (Pediatric) System does not replace a blood glucose meter. Always use the values from your blood glucose meter for treatment decisions. Blood glucose values may differ from sensor

glucose readings. Solely relying on the sensor glucose alerts and readings for treatment decisions could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

- Do not ignore symptoms of high and low glucose. If your sensor glucose alerts and readings do not match your symptoms, measure your blood glucose with a blood glucose meter even if your sensor is not reading in the high or low range. Solely relying on the sensor glucose alerts and readings for treatment decisions could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- In a pediatric clinical study, larger differences were observed between this CGM device and actual blood glucose values compared to those differences observed in the adult clinical study. Use your blood glucose meter for treatment decision.
- In a pediatric clinical study, a significant number of low glucose events were not detected by CGM. Do not rely solely on CGM alerts to detect low glucose.
- Do calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate and glucose alerts to become unreliable. This could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Do not ignore sensor fractures. Sensors may fracture on rare occasions. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—

at the insertion site. If you experience a broken sensor, please report this to our Technical Support department at **1.877.339.2664 or 1.858.200.0200 24 hours a day, 7 days a week**.

- Do not use the Dexcom G4 PLATINUM (Pediatric) System in pregnant women or persons on dialysis. The system **is not approved for use** in pregnant women or persons on dialysis and has not been evaluated in these populations. Sensor glucose readings may be inaccurate in these populations and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Do not use the Dexcom G4 PLATINUM (Pediatric) System in critically ill patients. It is not known how different conditions or medications common to the critically ill population may affect the performance of the system. Sensor glucose readings may be inaccurate in critically ill patients, and solely relying on the sensor glucose alerts and readings for treatment decisions could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Do not insert the sensor in sites other than the belly (abdomen) or upper buttocks. Other sites have not been studied and are not approved. Use in other sites might cause sensor glucose readings to be inaccurate and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Do not expect alerts from the Dexcom G4 PLATINUM (Pediatric) System until after the 2-hour startup. You will NOT get any sensor glucose readings or alerts until after the 2-hour startup ends AND you complete the startup calibration. During this time you might miss severe

hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

- Do not use your transmitter or receiver if it is damaged/cracked. This could create an electrical safety hazard or malfunction, which might cause electrical shocks.
- Store the sensor at temperatures between 36° F - 77° F for the length of the sensor's shelf life. You may store the sensor in the refrigerator if it is within this temperature range. The sensor should not be stored in a freezer. Storing the sensor improperly might cause the sensor glucose readings to be inaccurate, and you might miss severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Do not allow young children to hold the sensor, transmitter or transmitter kit box without adult supervision. The sensor and transmitter include small parts that may pose a choking hazard. Keep the transmitter kit box away from young children; it contains a magnet that should not be swallowed.

2.5 PRECAUTIONS

- Do not open the sensor package until you have washed your hands with soap and water, and let them dry. You may contaminate the insertion site and suffer an infection if you have dirty hands while inserting the sensor.
- Do not insert the sensor until you have cleaned the skin with a topical antimicrobial solution, such as isopropyl alcohol, and allowed the skin to dry. Inserting into unclean skin might lead to infection. Do not insert the sensor until the cleaned area is dry so the sensor adhesive will stick better.
- Avoid using the same spot repeatedly for sensor insertion.

Rotate your sensor placement sites, and do not use the same site for two sensor sessions in a row. Using the same site might cause scarring or skin irritation.

- Avoid inserting the sensor in areas that are likely to be bumped, pushed or compressed or areas of skin with scarring, tattoos, or irritation as these are not ideal sites to measure glucose. Insertion in those areas might affect sensor accuracy and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Avoid injecting insulin or placing an insulin pump infusion set within 3 inches of the sensor. The insulin might affect sensor accuracy and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Do not use the sensor if its sterile package has been damaged or opened. Using an unsterile sensor might cause infection.
- To calibrate the system, do enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Do not enter sensor glucose readings for calibration. Entering incorrect blood glucose values, blood glucose values obtained more than 5 minutes before entry, or sensor glucose readings might affect sensor accuracy and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Do not calibrate if your blood glucose is changing at a significant rate, typically more than 2 mg/dL per minute. Do not calibrate when your receiver screen is showing

the rising or falling single arrow or double arrow, which indicates that your blood glucose is rapidly rising or falling. Calibrating during significant rise or fall of blood glucose may affect sensor accuracy and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

- The system accuracy may be affected when your glucose is changing at a significant rate (e.g., 2-3 mg/dL/min or more than 3 mg/dL each minute), such as during exercise or after a meal.
- Avoid separating the transmitter and receiver by more than 20 feet. The transmission range from the transmitter to the receiver is up to 20 feet without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc. Types of obstruction differ and have not been tested. If your transmitter and receiver are farther than 20 feet apart or are separated by an obstruction, they might not communicate or the communication distance may be shorter and result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Keep the USB port cover on the receiver closed whenever the USB cable is not attached. If water gets into the USB port, the receiver could become damaged and stop displaying readings or providing alerts and result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Do not use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration. Alternative site blood glucose values may be different than those taken from a fingerstick blood glucose value and may not

represent the timeliest blood glucose value. Use a blood glucose value taken only from a fingerstick for calibration. Alternative site blood glucose values might affect sensor accuracy and result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

- Do not discard your transmitter. It is reusable. The same transmitter is used for each session until you have reached the end of the transmitter battery life.
- The Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver are not compatible with the SEVEN/SEVEN PLUS Transmitter and Receiver. Different generations will not connect with each other and will not work. Also make sure to use the correct version of Dexcom STUDIO with your system.

2.6 CAUTION

U.S. (Federal) law restricts the sale of the Dexcom G4 PLATINUM (Pediatric) System to sale by or on order of a physician.

chapter three

RISKS AND BENEFITS

3

CHAPTER 3: RISKS AND BENEFITS

3.1 RISKS

WARNINGS

- In a pediatric clinical study, larger differences were observed between this CGM device and actual blood glucose values compared to those differences observed in the adult clinical study. Use your blood glucose meter for treatment decision.
- In a pediatric clinical study, a significant number of low glucose events were not detected by CGM. Do not rely solely on CGM alerts to detect low glucose.

There are some known risks with using real-time CGM.

You will not get sensor glucose alerts when the alert function is turned off, your transmitter and receiver are out of range, or when your receiver is not showing sensor glucose readings. You might not notice alerts if you are unable to hear them or feel the vibration. Sometimes your sensor glucose reading may be slightly different than your blood glucose meter. For example, your blood glucose meter may show a blood glucose value of 78 mg/dL, but your sensor glucose reading may show as 82 mg/dL. If your low alert is set at 80 mg/dL, your system will not alert for a low glucose at this time because 82 mg/dL is still above your low alert setting. In most cases, the sensor glucose readings will move in the right direction and will alert you of a high or low shortly after. If you do not get an alert for any reason, and you do not take frequent blood glucose measurements with your blood glucose meter, you might not be aware of low or

high blood glucose levels. If this happens, and your blood glucose levels are very high or low, there is a remote chance you might need medical help.

Inserting the sensor and wearing the adhesive patch might cause infection, bleeding, pain or skin irritations (redness, swelling, bruising, itching, scarring or skin discoloration). There is a low chance of this happening. In the clinical study for the Dexcom G4 PLATINUM (Pediatric) System, only slight redness and swelling occurred in a few patients. If any of these events happen, you might feel discomfort in the area the sensor is inserted.

There is a remote chance that a sensor fragment could remain under your skin if the sensor breaks while you are wearing it. This did not happen in the clinical study for the Dexcom G4 PLATINUM (Pediatric) System. If you think a sensor has broken under your skin, contact your healthcare professional and call Dexcom's Technical Support. Sensor breakage may cause some anxiety, but it is not a significant medical risk.

3.2 BENEFITS

Real-time CGM provides benefits beyond the information you get from a blood glucose meter. It provides glucose readings every five minutes for up to seven days to help you detect trends and patterns in your glucose levels. This trend information can help you see where your glucose is now as well as where your glucose may be heading and how fast you may be getting there. Understanding your glucose trends may help you take action to help avoid high or low glucose values.

Alerts and the low alarm tell you when your glucose is outside of your target glucose range and may help you avoid low and high blood sugar. Rise and fall glucose alerts can also provide benefit by alerting you when your glucose is rapidly going down or up. This way you can be alerted to this information before you are too high or too low and take action to avoid it. Real-time CGM can help increase time in your target glucose range without increasing your time in the low or high glucose range.[1]

Real-time CGM can help improve diabetes control (lower A1c values, reducing glycemic variability and time spent in low and high blood glucose ranges)[1, 2, 3] which can help reduce diabetes related complications.[4, 5] These benefits can be seen especially with using real-time CGM at least 6 days per week[2] and can be sustained over time.[6] In some cases, patients perceived an increase in their quality of life and peace of mind when using real-time CGM as well as reporting a high satisfaction with CGM.[7]

[1] Garg S, Zisser H, Schwartz S, Bailey T, Kaplan R, Ellis S, Jovanovic L. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor: a randomized controlled trial. *Diabetes Care*. 2006; 29:44-50.

[2] JDRF CGM Study Group. Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes. *NEJM* 2008;359:1464-76.

[3] Battelino. Effect of continuous glucose monitoring of hypoglycemia in type 1 diabetes. *Diabetes Care* 2011; 34(4): 795-800.

[4] The Diabetes Control and Complications Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications of insulin-dependent diabetes mellitus. *N Eng J Med*. 1993; 329:997-1036.

[5] Ohkubo Y, Kishikawa H, Araki E, et al. Intensive insulin therapy prevents progression of diabetic microvascular complications in Japanese patients with non-insulin dependent diabetes mellitus: a randomized prospective 6-year study. *Diabetes Res Clin Pract.* 1995; 28:103-117.

[6] JDRF CGM Study Group. Sustained Benefit of Continuous Glucose Monitoring on A1c, Glucose Profiles, and Hypoglycemia in Adults With Type 1 Diabetes, *Diabetes Care* 2009; 32: 2047-2049.

[7] JDRF CGM Study Group. Quality-of-Life Measures in Children and Adults With Type 1 Diabetes. *Diabetes Care* 2010; 33: 2175-2177.

chapter four

CHARGING YOUR RECEIVER AND THE RECEIVER MAIN MENU

4

CHAPTER 4: CHARGING YOUR RECEIVER AND THE RECEIVER MAIN MENU

4.1 CHARGING YOUR RECEIVER BATTERY

The receiver battery is rechargeable and will last about 3 days with normal use before you need to charge it. Your battery life depends on how often you press your receiver buttons or get alerts. The receiver will tell you when the battery charge is low.

Low battery prompt

Charge the receiver battery using one of these options:

- Section 4.1.1: an AC power outlet
- Section 4.1.2: a personal computer with Windows® operating system (to charge your receiver from your PC, Dexcom STUDIO must be installed. For system requirements and more information, see the Dexcom website (www.dexcom.com) or the Dexcom STUDIO Software User's Guide.)

Only use the Dexcom battery charger provided in the receiver kit. Do not use any other battery charger.

Charge only from a USB port on your computer or the AC power adapter. Do not use an external USB hub. An external USB hub may not provide enough power to charge the receiver.

Fully charging an empty battery takes about 3 hours with the wall charger and about 5 hours with a computer. The battery does not need to be drained to charge fully.

You may use the receiver while it is charging with an AC power outlet or PC.

Charge your receiver battery before each sensor insertion. Periodically check your battery level to make sure it has enough charge.

If your battery drains, it will keep the time and date for 3 days without being charged. After 3 days, the receiver will prompt you to reset the time and date (see Chapter 5, Section 5.2, The Settings Menu).

When the receiver is used in a healthcare facility, charging must take place away from the patient.

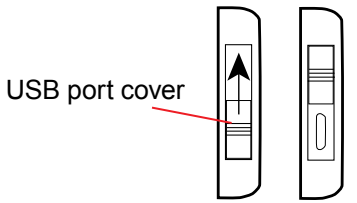
WARNING

Do not use the Dexcom G4 PLATINUM (Pediatric) System in critically ill patients. It is not known how different conditions or medications common to the critically ill population may affect the performance of the system. Sensor glucose readings may be inaccurate in critically ill patients, and solely relying on the sensor glucose alerts and readings for treatment decisions could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

4.1.1 CHARGING YOUR RECEIVER BATTERY FROM AN AC POWER OUTLET

To recharge your battery:

1. Plug the included USB cable into the AC power adapter.
2. Plug the AC power adapter into an AC power outlet.
3. Slide open the USB port cover on the side of the receiver to reach the port. Press down firmly with your thumb when sliding open the USB port cover.



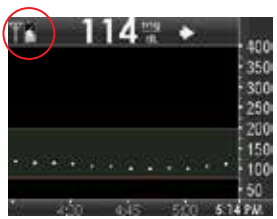
4. Plug the micro USB end of the cable into the receiver USB port.

Keep the USB port cover on the receiver closed whenever the USB cable is not attached.

5. The battery charging screen will show on the receiver.

Battery charging screen

6. After a few seconds the trend graph will show with the battery charging symbol ( ) in the upper left corner.



Battery charging symbol in upper left corner of trend graph

4.1.2 CHARGING YOUR RECEIVER BATTERY FROM A WINDOWS COMPATIBLE COMPUTER

You must install the Dexcom STUDIO software to charge your receiver from a computer. Please see the Dexcom STUDIO installation card for driver installation instructions.

1. Plug the included USB cable into your computer.
2. Plug the other end of the USB cable into the receiver.

3. The battery charging screen shows on the receiver.

Battery charging screen

4. After a few seconds, the trend graph screen will show the battery charging symbol in the upper left corner.

Battery charging symbol in upper left corner of trend graph

4.1.3 KNOWING YOUR RECEIVER IS CHARGED

As the battery charges, the battery charging symbol fills in.
When the battery is fully charged, the battery charging symbol is completely shaded.

Start Fully Charged

Battery charging symbol fills in as battery charges

4.2 RECEIVER MENU OPTIONS

The receiver's Main Menu lets you scroll through important menu options. This table explains the purpose of each option. More information on Main Menu options can be found in the chapters listed:

Receiver Main Menu Options

Menu	Purpose	User's Guide Reference
Trend Graph	To show the trend graphs. • The 3-hour trend graph is the default screen whenever you turn on the receiver.	Chapter 8
Start Sensor	To start a new sensor session. • This option only shows if you have entered a transmitter ID and you are not in the middle of a sensor session	Chapter 6
Enter BG	To enter your blood glucose values for calibration.	Chapter 7
Profiles	Profiles allow you to customize the sound and volume of alerts and alarm.	Chapter 9
Events	To enter personal information about meals, insulin, exercise, and health status.	Chapter 10
Alerts, High/Low	To change the settings for high and low alerts.	Chapter 9
Settings	To change the time, date and transmitter ID; to turn on the Share feature; to look up your Dexcom G4 PLATINUM (Pediatric) System hardware and software version numbers; to view transmitter battery status, last calibration value and sensor insertion time.	Chapter 5
Shutdown	To temporarily turn off all communication between your transmitter and receiver during a sensor session. You will not get sensor glucose readings, and it will not extend the life of your sensor.	Chapter 6

(continued on next page)

Receiver Main Menu Options (continued from page before)

Menu	Purpose	User's Guide Reference
Stop Sensor	To end a sensor session early. • This option only shows when you are in the middle of a sensor session. You will not get sensor glucose readings, and you must dispose of your sensor if you stop the session.	Chapter 13

See Chapter 18, Appendix I, Receiver Alerts, Alarm and Prompts, for a list of screens that may show on the receiver.

chapter five

DEXCOM G4 PLATINUM (PEDIATRIC) SYSTEM SETUP

5

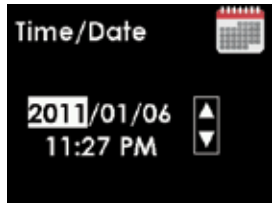
CHAPTER 5: DEXCOM G4 PLATINUM (PEDIATRIC) SYSTEM SETUP

This chapter helps you when you first set up your Continuous Glucose Monitoring system. Read this chapter before you start.

5.1 SETTING UP THE RECEIVER AND PAIRING WITH YOUR TRANSMITTER

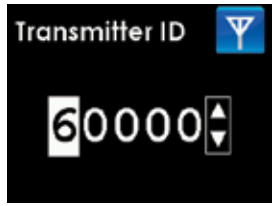
The Setup Wizard guides you through setup the first time you turn on your receiver.

1. Remove the transmitter from its packaging. Wait 10 minutes for the transmitter to turn on before setting up the receiver.
2. Make sure your receiver is fully charged (see Chapter 4, Section 4.1, Charging Your Receiver Battery).
3. Press the **SELECT** button on the receiver to turn it on. The Setup Wizard will guide you to enter the following setup information:
   a. Set the time and date. The date format is YYYY/MM/DD.
      (1) Press the **UP** or **DOWN** button to enter the current date and time.
      (2) Press the **RIGHT** or **SELECT** button to move to the next section.
      (3) Press the **SELECT** button to confirm time and date.



Time/Date setting screen

   b. Enter your transmitter ID.
      (1) Press the **UP** or **DOWN** button to enter your transmitter ID.
      (2) Press the **RIGHT** or **SELECT** button to move to the next space.



Transmitter ID setting screen

(3) Press the **SELECT** button after you enter the last number or letter to confirm the transmitter ID.

Your transmitter ID is a unique code with 5 numbers and/or letters found in the following locations:

- On the transmitter box label
- On the bottom of the transmitter

c. Set your low and high glucose alert values. Your low and high glucose alerts are pre-set to 80 mg/dL and 200 mg/dL but can be changed.

Low Alert setting screen

High Alert setting screen

(1) Press the **UP** or **DOWN** button to select your alert level. The low alert can be changed in steps of 5 mg/dL, and the high alert can be changed in steps of 10 mg/dL.

(2) Press the **SELECT** button to confirm your alert level.

- You can also change your alert levels in the Alerts menu.
- The unit of measure (mg/dL) is not adjustable.
- If you need to change the time, date or transmitter ID after you complete the Setup Wizard see Section 5.2, The Settings Menu.

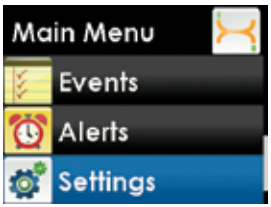
The Setup Wizard is now complete. To start using your Dexcom G4 PLATINUM (Pediatric) CGM System you must insert a sensor (see Chapter 6, Inserting a Sensor and Starting a Sensor Session).

5.2 THE SETTINGS MENU

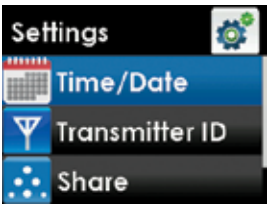
The Settings menu lets you change the time, date or transmitter ID. The Setup Wizard only works the first time you turn on your receiver, but you can always use the Settings menu.

5.2.1 GETTING TO THE SETTINGS MENU

1. Press the **SELECT** button to turn on the receiver. The 3-hour trend graph shows.
2. Press the **SELECT** button to see the Main Menu.
3. From the Main Menu, press the **UP** or **DOWN** button to scroll to "Settings" and press the **SELECT** button. The Settings menu shows:



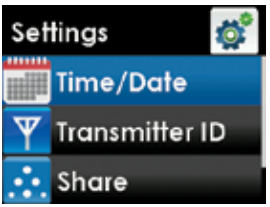
Main Menu,
Settings highlighted



Settings menu

5.2.2 SETTING YOUR RECEIVER TIME AND DATE

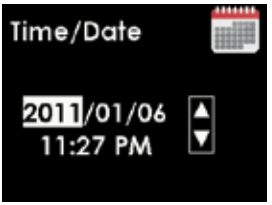
1. From the Settings menu, press the **UP** or **DOWN** button to scroll to "Time/Date," and press the **SELECT** button.



Settings menu,
Time/Date highlighted

2. Press the **RIGHT** button to highlight each value in the date and time.
3. Press the **UP** or **DOWN** button to make any changes.
4. Press the **RIGHT** button to move to the next value.

The date format is YYYY/MM/DD.



Time/Date setting screen, year highlighted

5. Press the **SELECT** button after choosing "AM" or "PM." You will return to the Settings menu.

You might need to reset the receiver's time and date if the rechargeable battery drains. If this happens, the receiver will alert you and automatically take you to the Time/Date setting screen.

5.2.3 ENTERING YOUR TRANSMITTER ID

Any time you switch to a new transmitter and/or receiver you must enter the transmitter ID into your receiver. The transmitter ID is a series of 5 numbers and/or letters that can be found in the following locations:

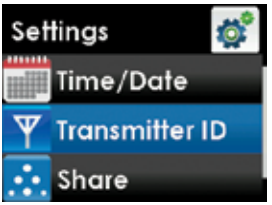
- On the transmitter box label
- On the bottom of the transmitter

If you cannot find your transmitter ID, please contact Dexcom Technical Support (see Chapter 15, User Assistance).

You can only set your transmitter ID when you are not in a sensor session. During a sensor session, "Transmitter ID" will not be an option on the Settings menu.

To enter the transmitter ID follow these steps:

1. From the Settings menu, press the **UP** or **DOWN** button to scroll to “Transmitter ID” and press the **SELECT** button.



Settings menu, Transmitter ID highlighted

2. Start with the first number or letter (do not enter “SN”):
   a. Press the **UP** or **DOWN** button to show the correct number or letter.
   b. Press the **RIGHT** or **SELECT** button to move to the next value and repeat step a.
   c. Continue repeating steps a and b to enter the whole transmitter ID.
   d. Press the **SELECT** button after you enter the last number or letter. You will return to the Settings menu.

Transmitter ID setting screen, first digit highlighted

NOTE: The “Transmitter ID” menu option is marked with an antenna symbol as a graphical flag; it does not tell you whether the transmitter and receiver are communicating. The “Transmitter ID” menu option only shows when you are not in a sensor session. See Section 5.4 for the antenna symbol that shows whether the transmitter and receiver are communicating.

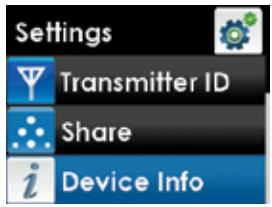
5.2.4 TURNING ON SHARE ON YOUR RECEIVER

Please see the Pairing Receiver section in Chapter Two of your Dexcom Share User Manual to learn how to turn on the Share feature on your Dexcom G4 PLATINUM (Pediatric) Receiver with Share.

5.3 CHECKING INFORMATION ABOUT YOUR DEXCOM G4 PLATINUM (PEDIATRIC) SYSTEM

You can check your receiver for information about your CGM system at any time.

1. From the Settings menu, press the **UP** or **DOWN** button to scroll to “Device Info.”
2. Press the **SELECT** button. Information about your sensor session and system will show.



Settings menu, Device Info highlighted

3. Scroll down to see all of the Device Info:
    - Insertion Time
    - Last Calibration
    - Transmitter Battery
    - Transmitter ID
    - Serial Number
    - Part Number
    - Part Revision
    - Software Number
    - Software Revision

Device Info screen

4. Press the **LEFT** button to return to the Settings menu.

5.4 TRANSMITTER AND RECEIVER COMMUNICATION

When you are in a sensor session, you can check that the receiver and transmitter are communicating.

CONTRAINDICATION

Remove the Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver before Magnetic Resonance Imaging (MRI), Computed Tomograph (CT) scan, or diathermy treatment. The device is MR Unsafe. Do not bring any portion of the device into the MR environment. The Dexcom G4 PLATINUM System has not been tested during MRI or CT scans or with diathermy treatment. The magnetic fields and heat could damage the device so that it might not display sensor glucose readings or provide alerts, and you might miss a low or high blood glucose value.

PRECAUTION

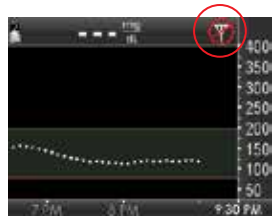
Avoid separating the transmitter and receiver by more than 20 feet. The transmission range from the transmitter to the receiver is up to 20 feet without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc. Types of obstruction differ and have not been tested. If your transmitter and receiver are farther than 20 feet apart or are separated by an obstruction, they might not communicate or the communication distance may be shorter and result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

5

Press the **SELECT**, **LEFT** or **RIGHT** button to see the trend graph. This antenna symbol shows that the transmitter and receiver are communicating.

Antenna symbol appears in upper left of trend graph

This out of range symbol shows the transmitter and receiver are not communicating.



Out of range symbol appears in upper right of trend graph

6

chapter six

INSERTING A SENSOR AND STARTING A SENSOR SESSION

6

CHAPTER 6: INSERTING A SENSOR AND STARTING A SENSOR SESSION

You need a sensor, a transmitter, and a receiver to use your Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring System. You also need a blood glucose meter and test strips for calibration. The blood glucose meter and test strips are not provided in the Dexcom G4 PLATINUM (Pediatric) System. The sensor continuously measures and displays your sensor glucose readings for up to 7 days. The following sections will show you how to insert the sensor and start a new continuous glucose monitoring session.

Please review the tutorial on the disc in your kit. The tutorial is also available online at www.dexcom.com.

WARNING

Do not ignore sensor fractures. Sensors may fracture on rare occasions. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the insertion site. If you experience a broken sensor, please report this to our Technical Support department at **1.877.339.2664 or 1.858.200.0200 24 hours a day, 7 days a week**.

For patients undergoing an MRI with a retained wire broken off from a Dexcom G4 PLATINUM Sensor, in-vitro MRI testing did not detect any safety hazards. There was no significant migration or heating of the wire and imaging artifacts were limited to the area around the wire.

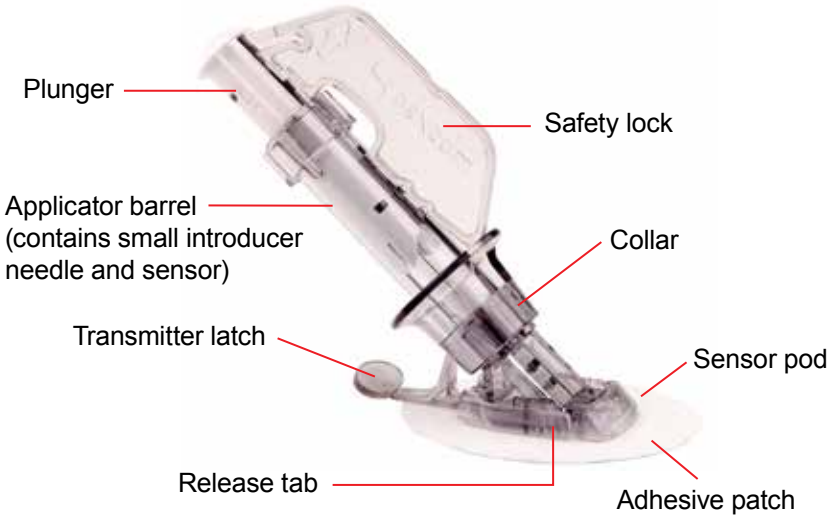
6.1 BEFORE YOU START

- Make sure the correct transmitter ID has been entered into your receiver (see Chapter 5, Section 5.2, The Settings Menu). You do not need to re-enter the transmitter ID each time you start a sensor session.
- Check the expiration date on the sensor package label. The format is YYYY-MM-DD. Insert sensors on or before the end of the expiration date calendar day.
- Follow your blood glucose meter's manufacturer's instructions to make sure you are getting accurate blood glucose values for calibration.
- Wipe the bottom of the transmitter with a damp cloth or isopropyl alcohol wipe. Place the transmitter on a clean, dry cloth, and air dry for 2-3 minutes.
- Make sure your blood glucose meter and receiver date and time match.

WARNING

Store the sensor at temperatures between 36° F - 77° F for the length of the sensor's shelf life. You may store the sensor in the refrigerator if it is within this temperature range. The sensor should not be stored in a freezer. Storing the sensor improperly might cause the sensor glucose readings to be inaccurate, and you might miss severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

Review the sensor applicator picture before using a new sensor.



6.2 REMOVING THE SENSOR FROM ITS PACKAGING

PRECAUTION

Do not use the sensor if its sterile package has been damaged or opened. Using an unsterile sensor might cause infection.

- Wash your hands thoroughly, and dry them.
- Carefully remove the sensor from its packaging. Look closely at the sensor to make sure it is not damaged.
- The applicator is for single use and is disposable.
- The safety lock prevents you from releasing the needle accidentally before you are ready.

6.3 CHOOSING AN INSERTION SITE

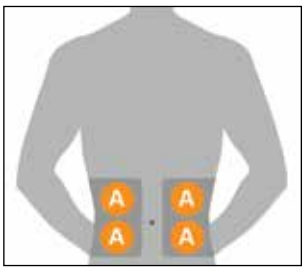
PRECAUTIONS

- Avoid inserting the sensor in areas that are likely to be bumped, pushed or compressed or areas of skin with scarring, tattoos, or irritation as these are not ideal sites to measure glucose. Insertion in those areas might affect sensor accuracy and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- Avoid injecting insulin or placing an insulin pump infusion set within 3 inches of the sensor. The insulin might affect sensor accuracy and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

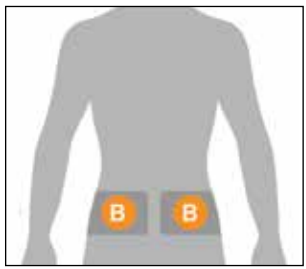
Review the tutorial disc for more help to learn how to insert your sensor.

Choose a site to place the sensor. Insert in the belly (front of body, option A) or the upper buttocks (back of body, option B).

No other sensor insertion sites have been tested and we do not know how well the sensor will work in other sites.



Front of body, sensor site option A



Back of body, sensor site option B

The ideal sensor insertion site for you may be based on your body type, activity, sensitivities, and other personal and physical traits. You can choose a site above or below your belt line. The best areas to insert your sensor are usually flat and “pinchable.” Avoid sensor insertion where something may rub or press against the sensor. For example, avoid sensor insertion along the waist band and seat belt strap, in or near the belly button, on the upper buttocks near the waist/belt or too low on the buttocks where you sit.

PRECAUTION

Avoid using the same spot repeatedly for sensor insertion. Rotate your sensor placement sites, and do not use the same site for two sensor sessions in a row. Using the same site might cause scarring or skin irritation.

- Choose an area at least 3 inches from your insulin pump infusion set or injection site.
- You may need to shave the area where you plan to put the sensor so the adhesive patch sticks securely.
- Make sure there are no traces of lotions, perfumes or medications on the skin where you place the sensor.

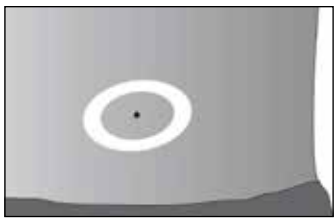
For more help on ideal sensor insertion sites for you, contact your healthcare professional.

6.4 PLACING THE SENSOR

WARNINGS

- Do not use the Dexcom G4 PLATINUM (Pediatric) System for treatment decisions, such as how much insulin you should take. The Dexcom G4 PLATINUM (Pediatric) System does not replace a blood glucose meter. Always use the values from your blood glucose meter for treatment decisions. Blood glucose values may differ from sensor glucose readings. Solely relying on the sensor glucose alerts and readings for treatment decisions could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.
- In a pediatric clinical study, larger differences were observed between this CGM device and actual blood glucose values compared to those differences observed in the adult clinical study. Use your blood glucose meter for treatment decision.
- In a pediatric clinical study, a significant number of low glucose events were not detected by CGM. Do not rely solely on CGM alerts to detect low glucose.

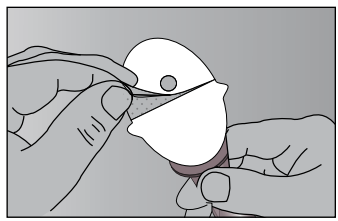
1. Clean your skin at the sensor placement site with an alcohol wipe. Make sure the area is clean and completely dry before you insert the sensor.



Step 1. (Optional) Use skin prep in doughnut shape, and insert in clean skin at center

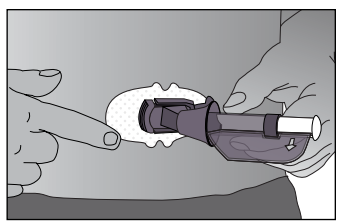
NOTE: Skin preparation or adhesive products (Mastisol®, Skin Tac™) are optional. If you use an optional skin preparation or adhesive product, place it on the skin in a "doughnut" shape where you will place the sensor adhesive patch. Insert the sensor through the clean skin at the center of the doughnut where it is free of skin preparation or adhesive products. Let dry (skin may feel slightly sticky).

2. Remove the adhesive backing from the sensor pod one half at a time, using the white tabs on the backing. Hold the sensor by the applicator barrel, and try not to touch the sticky adhesive patch.



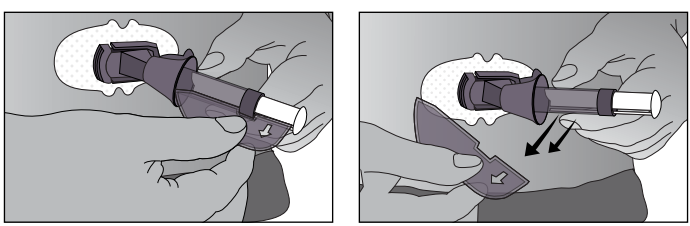
Step 2. Remove the adhesive backing

3. Place the sensor horizontally, NOT vertically, on your skin.
4. Move your fingers around the adhesive patch to secure the tape to your skin.



Step 3 and 4. Adhere the sensor on the skin

5. Hold the applicator, and pull the safety lock straight out away from the applicator, in the direction of the arrows in the picture.



Step 5. Remove the safety lock

6. Save the safety lock to help you remove the transmitter at the end of your sensor session. The safety lock can be used for transmitter removal but is not required. When your glucose monitoring session is over, follow the steps in Chapter 11, Section 11.3, Transmitter Removal, with or without the safety lock.

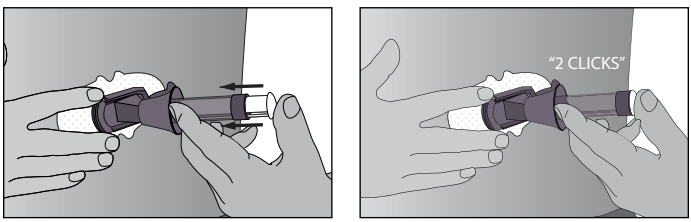
NOTE: Contact your healthcare professional for specific questions regarding the use of medical tape, barrier wipes and/or other adhesives as it relates to your use of Dexcom CGM.

6.5 SENSOR INSERTION

You are ready to insert the sensor after you place the applicator on your skin and remove the safety lock. To insert your sensor follow these steps:

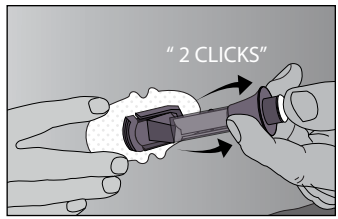
1. Place the fingers of one hand at the edge of the white adhesive (at the opposite side of the sensor from the transmitter latch). You may pinch up on your skin using this hand. Do not pinch up in the middle section of the plastic base.
2. While still pinching, use your other hand to place two fingers above the collar on the applicator barrel so they are resting above the collar.
3. Place your thumb on the white plunger. Push the plunger down completely, making sure it is flush against the applicator barrel. You should hear **2 clicks**. This inserts the needle and sensor under your skin.

When you are pushing down on the plunger, do not pull back on the collar.



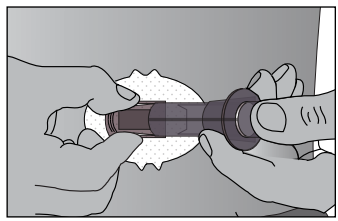
Steps 1-3. Push down the plunger - insert the needle and sensor

4. Keep pinching up on your skin with one hand. With your other hand, place two fingers under the collar. Keep your thumb lightly on top of the white plunger, and pull the collar back towards your thumb until you hear **2 clicks** or cannot pull back any more. This leaves the sensor under your skin and removes the needle from your body.



Step 4. Pull back the collar - retract the needle

5. Squeeze the center of the ribbed release tabs on the sides of the sensor pod to remove the applicator barrel. Only the sensor pod will be left on your body.



Step 5. Release the applicator barrel

- Make sure the transmitter latch is down (against your body) before squeezing the tabs to remove the applicator barrel.
- Squeeze the center of the ribbed part of the release tabs.
- While squeezing the tabs, rock the applicator barrel forward and out away from your body.

If you have any problems with insertion, save the sensor and applicator and contact Dexcom Technical Support (see Chapter 15, User Assistance).

6.6 TRANSMITTER ATTACHMENT

You must snap the transmitter into the sensor pod after you insert your sensor. Follow these steps to attach your transmitter.

1. Wipe and dry the bottom of the transmitter with a damp cloth or an alcohol wipe before every use.

Do not to touch the metal circles on the bottom of the transmitter with your skin.

Do not to scratch the bottom of the transmitter as scratches may compromise the waterproof seal.

2. Place the transmitter in the sensor pod (with the flat side down, and the narrower side away from the transmitter latch).

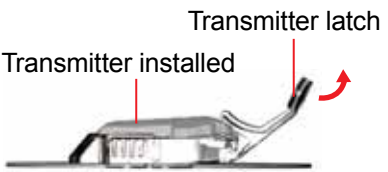
Install transmitter in sensor pod

3. Snap in the transmitter:

   a. With one hand, you may want to pinch up on your skin at the front edge of the white adhesive.

   b. Place one finger on the transmitter to keep it in place.

   c. With your other hand, pull the transmitter latch up and forward, over the transmitter, to snap it into place. The transmitter should lie flat in the sensor pod.



Side view of transmitter in sensor pod

   • Make sure you hear **2 clicks** when you snap the transmitter in place. If it is not fully snapped in, this may lead to a poor connection and let fluids to get under the transmitter. This can lead to inaccurate sensor glucose readings.

   d. Release your pinch on the adhesive edge at this time.

   e. Make sure the transmitter is secure by sliding your fingers under each long side of the sensor pod and pressing down on the transmitter with your thumb of the same hand, like you are pinching it.

4. Hold the sides of your sensor pod with one hand. Remove the transmitter latch with your other hand by quickly twisting off the latch away from your body.

Twist transmitter latch up or down

5. **Do not remove the transmitter from the sensor pod while the pod is attached to your skin.**

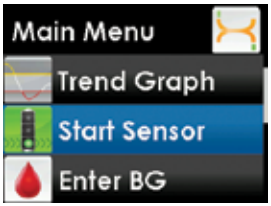
6.7 STARTING A SENSOR SESSION

WARNING

In a pediatric clinical study, larger differences were observed between this CGM device and actual blood glucose values compared to those differences observed in the adult clinical study. Use your blood glucose meter for treatment decision.

Follow these steps to tell the receiver that you inserted a new sensor.

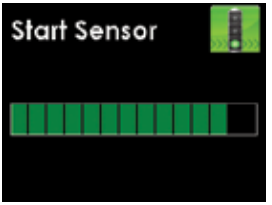
1. Press the **SELECT** button to turn on the receiver.
2. From any trend graph, press the **SELECT** button to see the Main Menu.
3. Press the **DOWN** button to highlight "Start Sensor."
   - The "Start Sensor" menu option will disappear from the Main Menu after you select it. The option will only come back after an active sensor session ends. If you do not see the "Start Sensor" option on your menu screen, you can continue your



Main Menu, Start Sensor highlighted

current session or stop the session (refer to Chapter 13, Section 13.6, Sensor Shut-off Troubleshooting).

4. Press the **SELECT** button to confirm the start of a new sensor session. The Start Sensor "thinking" screen lets you know your sensor 2-hour startup has begun.



Start Sensor "thinking" screen

5. After you start your sensor session, this screen appears as a reminder of the differences in CGM performance between two different clinical studies in adults and pediatrics. This screen appears each time you start a new sensor session.

Sensor Started warning screen

6. Press **SELECT** to confirm this message. Your receiver returns to the 3-hour trend graph.
7. Check your receiver 10 minutes after starting your sensor session to make sure your receiver and transmitter are communicating. The antenna symbol should be in the upper left corner of trend graph. If the out of range symbol shows in the upper right corner of the trend graph, see Chapter 13, Section 13.10, Out of Range/No Antenna.

Antenna symbol should appear in upper left of trend graph

8. You will not get sensor glucose readings or alerts until your 2-hour startup period ends and you complete your first calibrations. See Chapter 7, Section 7.3, Startup Calibration.

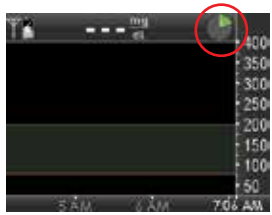
6.8 SENSOR STARTUP PERIOD

The sensor needs a 2-hour startup period to adjust to being under the skin.

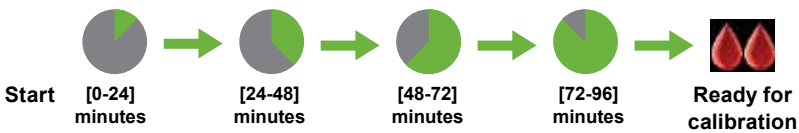
Your trend graph shows a 2-hour countdown symbol in the upper right corner.

1. Press **SELECT** during the startup period to turn the on receiver display and see this symbol.

The countdown symbol fills in over time to show that you are getting closer to the first calibration time. You will not get sensor glucose readings, alerts and alarm during the countdown.



Countdown symbol appears in upper right of trend graph



Countdown symbol fills in during sensor startup

If you see the out of range symbol at the top of the screen during the 2-hour startup, review the following troubleshooting tips:

- Make sure your receiver and transmitter are within 20 feet of each other without obstruction. Check in 10 minutes to see if the antenna symbol shows in the upper left corner of the receiver screen.
- If the receiver and transmitter are still not communicating, check the device information screen to make sure the correct transmitter ID is entered into your receiver (see Chapter 5, Section 5.2, The Settings Menu).
- If the correct transmitter ID is in your receiver and the receiver and transmitter are still not communicating, contact Dexcom Technical Support (see Chapter 15, User Assistance).

At the end of the 2-hour startup period the receiver lets you know it is time to calibrate your sensor. Chapter 7, Calibrating Your Dexcom G4 PLATINUM (Pediatric) System, tells you how to calibrate your sensor.

6.9 TAPING THE SENSOR POD

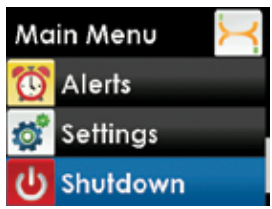
The right way to use tape for extra support

The sensor pod should stay on your skin using its own adhesive. But, if the patch is peeling up, you can use medical tape (such as Blenderm™, Tegaderm™, Smith & Nephew IV3000®, 3M™ tape) for extra support. If you use tape, only tape over the white adhesive patch on all sides for even support. Do not tape over the transmitter or any of the plastic parts of the sensor pod. Do not tape under the sensor pod or leave any substance on the skin where you insert the sensor.

6.10 TEMPORARY RECEIVER SHUTDOWN

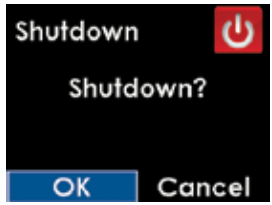
There may be times when you want to shut down your receiver temporarily. Shutdown stops all communication between the transmitter and receiver and turns the receiver off. You will not receive sensor glucose readings or **any** alerts or alarm while the receiver is shut down, but your current sensor session will continue. Follow these steps to shut down your receiver:

1. From the Main Menu, scroll to highlight "Shutdown." Press the **SELECT** button.



Main Menu, Shutdown highlighted

2. Confirm that you want to shut down your receiver.
   a. If you want to shut down, press the **LEFT** button to highlight “OK,” and then press the **SELECT** button.
   b. If you want to cancel the shutdown, press the **SELECT** button (with “Cancel” highlighted) to return to the Main Menu.



Shutdown screen, OK highlighted

To turn the receiver back on and resume communication with the transmitter, press the **SELECT** button. It may take up to 20 seconds for the display to turn back on.

Remember that your alerts and low glucose alarm will not work when the receiver is shut down.

Shutting down the receiver does not extend the sensor life beyond 7 days. Your sensor session will stop 7 days after you started the sensor session.

6.11 THE DEXCOM G4 PLATINUM (PEDIATRIC) SYSTEM AND WATER

Your sensor is water resistant when showering, bathing or swimming if the transmitter is fully snapped in. The sensor has been tested to be water resistant when submerged for up to 8 feet and up to 24 hours.

Keep the receiver dry. Do not spill fluids on it or drop it into fluids. **Keep the micro USB port cover closed to help prevent fluid from getting inside the receiver.** Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub or water bed.

If your receiver gets wet, make sure the speaker and vibrate mode are still working. You can do this using the Try It option in the profiles menu. See Chapter 9, Section 9.3, Alert Profiles.

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7

chapter seven

CALIBRATING YOUR DEXCOM G4 PLATINUM (PEDIATRIC) SYSTEM

7

CHAPTER 7: CALIBRATING YOUR DEXCOM G4 PLATINUM (PEDIATRIC) SYSTEM

You must calibrate Dexcom G4 PLATINUM (Pediatric) System sensor glucose readings to your blood glucose meter.

CONTRAINDICATION

Taking medications with acetaminophen (such as Tylenol) while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.

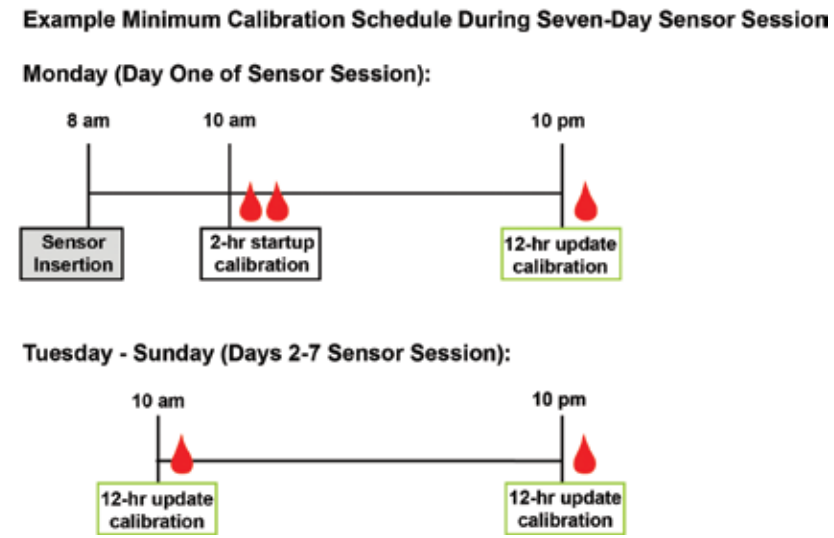
7.1 CALIBRATION OVERVIEW

Your receiver needs calibrations to display continuous sensor glucose readings and trend information. There are important times when you **must** calibrate:

1. 2-hour startup: 2 hours after you insert your sensor
2. 12-hour update: every 12 hours after the 2-hour startup calibration
3. More information needed or other reasons

When calibrating, you must enter your blood glucose values into the receiver by hand. You can use any commercially available blood glucose meter. You must calibrate with accurate blood glucose meter values to get accurate sensor glucose readings.

On the first day of your sensor session, you must enter 2 blood glucose values into your receiver. You must enter 1 blood glucose value calibration 12 hours after your startup calibration. You must enter 1 blood glucose value every 12 hours. The receiver will remind you when it needs these calibrations. You may be prompted to enter additional blood glucose values as needed.



Example Minimum Calibration Schedule During Seven-Day Sensor Session

PRECAUTION

Do not use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration. Alternative site blood glucose values may be different than those taken from a fingerstick blood glucose value and may not represent the timeliest blood glucose value. Use a blood glucose value taken only from a fingerstick for calibration. Alternative site blood glucose values might affect sensor accuracy and result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

7.2 HOW TO CALIBRATE

You must enter the exact blood glucose value from your meter for each calibration. Blood glucose values must be between 40-400 mg/dL and must have been taken within the past 5 minutes.

- Make sure either a sensor glucose reading or a calibration needed symbol shows at the top of the trend graph before calibrating.
- Your sensor can be calibrated if your meter glucose is 40 mg/dL or above. For safety reasons, if your blood glucose is low, first treat your low blood sugar.
- Always make sure the antenna symbol is in the upper left corner of the trend graph before you enter blood glucose values for calibration.
- Always use the same meter to calibrate that you routinely use to measure your blood glucose. Do not switch your meter in the middle of a sensor session. Blood glucose meter and strip accuracy vary between blood glucose meter brands.
- The accuracy of the blood glucose meter value used for calibration may affect the accuracy of sensor glucose readings.

WARNING

Do calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate and glucose alerts to become unreliable. This could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

PRECAUTION

Do not calibrate if your blood glucose is changing at a significant rate, typically more than 2 mg/dL per minute. Do not calibrate when your receiver screen is showing the rising or falling single arrow or double arrow, which indicates that your blood glucose is rapidly rising or falling. Calibrating during significant rise or fall of blood glucose may affect sensor accuracy and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

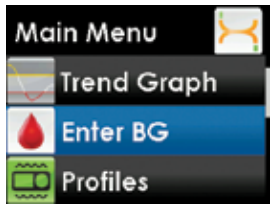
PRECAUTION

To calibrate the system, do enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Do not enter sensor glucose readings for calibration. Entering incorrect blood glucose values, blood glucose values obtained more than 5 minutes before entry, or sensor glucose readings might affect sensor accuracy and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

Only use blood glucose values between 40-400 mg/dL for calibration. If the blood glucose value you enter is outside of this range, the receiver will not calibrate. You must wait until your blood glucose is in this range to calibrate.

These steps show you how to enter your blood glucose values for calibration:

1. Wash and dry your hands, make sure your glucose test strips are not expired and have been stored properly, and make sure your meter is properly coded (if required).
2. Take a blood glucose measurement using your meter.
   - Carefully apply the blood sample to the test strip following your meter or test strip instructions.
3. From any trend graph, press the **SELECT** button to see the Main Menu.
4. Use the **UP** or **DOWN** button to scroll until you highlight "Enter BG."
   - "Enter BG" will be the second Main Menu option when you are in the middle of a sensor session.
5. Press the **SELECT** button to choose this option. You will see a screen with a blood drop and a number in mg/dL units.
   a. When the receiver does not have a recent sensor glucose reading the default is 120 mg/dL.
   b. If there has been a sensor glucose reading in the past 15 minutes, the Enter BG screen shows your current sensor glucose reading. **Do not use the current sensor glucose reading for calibration.** Use only blood glucose values from your meter.
6. Use the **UP** or **DOWN** button to scroll until you see the correct blood glucose value, and then press the **SELECT** button.



Main Menu, Enter BG highlighted

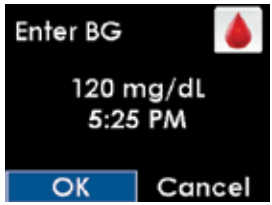
Enter BG screen, default is 120 mg/dL

7. **Confirm that the blood glucose value you entered is correct. Entering incorrect values may affect the sensor accuracy.**

   a. Press the **SELECT** button if the blood glucose value displayed is correct.

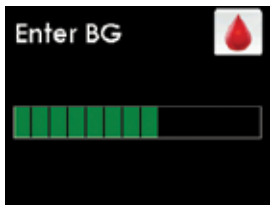
   b. If the blood glucose value shown is incorrect, press the **RIGHT** button to highlight “Cancel” then press the **SELECT** button to return to the Enter BG screen. Repeat the steps to enter the correct blood glucose value.

   c. If you do not press the **SELECT** button, the receiver will “time out” and no blood glucose value will be recorded for calibration.



Enter BG screen,
OK highlighted to confirm

8. The Enter BG “thinking” screen lets you know the blood glucose value is being used for calibration.



Enter BG
“thinking” screen

9. For 2-hour startup calibration, repeat these steps for the second blood glucose value.

A sensor glucose reading appears on the receiver right away, and sensor glucose readings are updated every 5 minutes.

If readings do not appear immediately, see Chapter 13, Section 13.2, Calibration Troubleshooting.

PRECAUTION

To calibrate the system, do enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Do not enter sensor glucose readings for calibration. Entering incorrect blood glucose values, blood glucose values obtained more than 5 minutes before entry, or sensor glucose readings might affect sensor accuracy and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

7.3 STARTUP CALIBRATION

Two hours after you start the sensor session (see Chapter 6, Section 6.7, Starting a Sensor Session) the receiver tells you that you need to calibrate by showing the startup calibration prompt. This means you need to calibrate with 2 separate blood glucose values from your meter. **You will not see sensor glucose readings until the receiver accepts the blood glucose values.**

Startup calibration prompt

1. When you see this screen, press the **SELECT** button to clear it.
   a. The startup calibration symbol will stay at the top of the trend graph until you calibrate.
   b. The system will re-alert you every 15 minutes until you enter the blood glucose values.
   c. If you do not clear the prompt, the system will re-alert you every 5 minutes.

2. Take 2 separate blood glucose measurements with your meter, and enter the blood glucose values into the receiver (see Chapter 7, Section 7.2, How to Calibrate).

7.4 12-HOUR CALIBRATION UPDATE

Calibrate your system at least every 12 hours after your first calibration (2-hour startup calibration) to make sure your sensor glucose readings remain accurate and close to your blood glucose meter values. You can enter blood glucose values earlier than 12 hours if you want. If you have not entered any blood glucose values in the past 12 hours, the receiver will ask you to enter a blood glucose value to update its calibration.

WARNING

Do calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate and glucose alerts to become unreliable. This could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

The following steps show you how to enter this calibration.

1. When you see this screen, press the **SELECT** button to clear it.
   a. The calibration needed symbol will stay at the top of the trend graph until you calibrate.
   b. The system will re-alert every 15 minutes until you enter the blood glucose values.

Calibration prompt

2. Take 1 blood glucose measurement with your meter, and enter the blood glucose value into the receiver. If this screen reappears soon, see Chapter 13, Section 13.2, Calibration Troubleshooting.

7.5 OTHER REASONS YOU MAY NEED TO CALIBRATE

You may need to calibrate when your system did not accept the last calibration or your blood glucose value is very different from the sensor glucose reading.

When you see this calibration prompt it means it is time to calibrate with a single blood glucose value.

Take 1 blood glucose measurement with your meter, and enter the blood glucose into the receiver. If this screen reappears soon, see Chapter 13, Section 13.2.1, Types of Calibration Prompts.

Calibration prompt

These screens show calibration errors (see Chapter 13, Section 13.3, Calibration Error Troubleshooting).

Wait 15 minutes calibration error screen

Wait 1 hour calibration error screen

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chapter eight

SENSOR GLUCOSE READINGS AND TRENDS

CHAPTER 8: SENSOR GLUCOSE READINGS AND TRENDS

This chapter teaches you how to view your sensor glucose readings and trend information. The trend graph provides additional information that your blood glucose meter does not. It shows your current glucose value, the direction it is changing and how fast it is changing. The trend graph can also show you where your glucose has been over time.

WARNINGS

- In a pediatric clinical study, larger differences were observed between this CGM device and actual blood glucose values compared to those differences observed in the adult clinical study. Use your blood glucose meter for treatment decision.
- In a pediatric clinical study, a significant number of low glucose events were not detected by CGM. Do not rely solely on CGM alerts to detect low glucose.

CONTRAINDICATION

Taking medications with acetaminophen (such as Tylenol) while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.

Your blood glucose meter and sensor measure glucose from two different types of body fluids: blood and interstitial fluid. Therefore, readings from your blood glucose meter and sensor may not match.

8

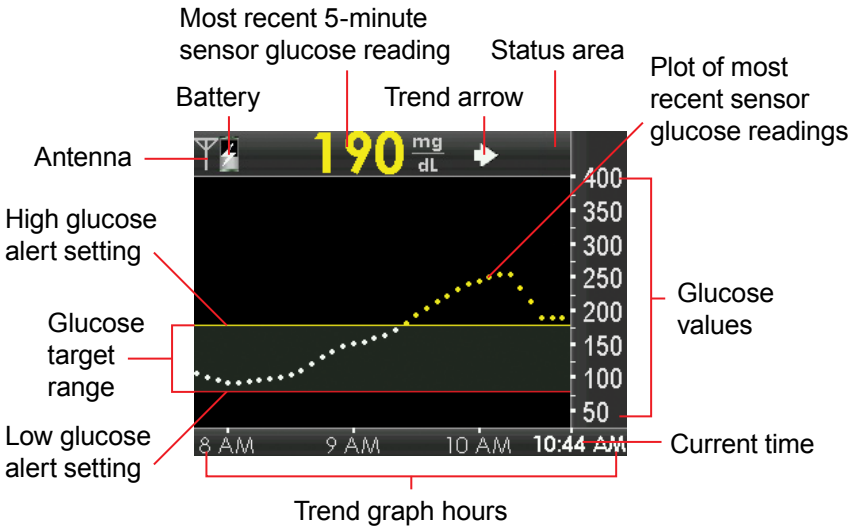
The greatest benefit you get from using your Dexcom G4 PLATINUM (Pediatric) System will come from the trending information. It is important that you focus on the trends and rate of change on your receiver, rather than the exact sensor glucose reading.

If you have trouble reading your receiver in bright sunlight, find a shady spot.

> **WARNING**
>
> Do not use the Dexcom G4 PLATINUM (Pediatric) System for treatment decisions, such as how much insulin you should take. The Dexcom G4 PLATINUM (Pediatric) System does not replace a blood glucose meter. Always use the values from your blood glucose meter for treatment decisions. Blood glucose values may differ from sensor glucose readings. Solely relying on the sensor glucose alerts and readings for treatment decisions could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

8.1 SENSOR GLUCOSE READINGS

Press the **SELECT** button to wake up the receiver screen and see the home screen (the 3-hour trend graph). The 3-hour trend graph shows the following:



EXAMPLE: 3-Hour Trend Graph Screen

- Each “dot” on the trend graph is a sensor glucose reading reported every 5 minutes.
- The trend graph shows the current time.
- The status area shows needed calibration updates, calibration errors and sensor glucose reading issues.
- Your high alert setting shows as a yellow line across the trend graph.
- Your low alert setting shows as a red line across the trend graph.
- The gray zone highlights your target glucose range, based on your high and low glucose alert settings.
- Your current sensor glucose reading is red if it is low and yellow if it is high, based on your high and low glucose alert settings.
- If your low glucose alert is not set and your glucose is 55 mg/dL or lower, your glucose value is red.
- If your sensor glucose readings are in between your high and low glucose alert settings, the glucose value is white.

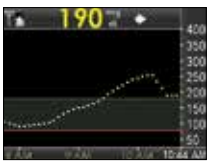
- The dots on your trend graph change colors based on your high and low alert settings.

You can view your past glucose information on the 1, 3, 6, 12, and 24 hour trend graphs by pressing the **UP** or **DOWN** button.

- Your system only reports glucose information between 40-400 mg/dL. Your trend graph shows a flat line or dots at 400 or 40 mg/dL when your glucose is outside this range.

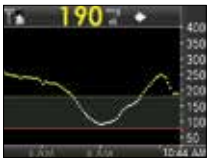
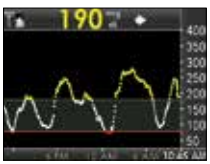
The sensor glucose reading is in milligrams per deciliter (mg/dL) unit

Which Trend Graph Do You See?

(Scroll up from the 3-hour graph to reach the 1-hour graph)	
	1-Hour Trend Graph: The 1-hour trend graph shows your current sensor glucose reading and the last 1 hour of sensor glucose readings.
	**3-Hour Trend Graph:** The 3-hour trend graph shows your current sensor glucose reading and the last 3 hours of sensor glucose readings.

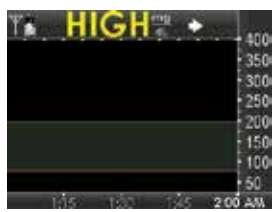
(continued on next page)

Which Trend Graph Do You See? (continued from page before)

(Scroll down from the 3-hour graph to reach the 6-hour graph)
 **6-Hour Trend Graph:** The 6-hour trend graph shows your current sensor glucose reading and the last 6 hours of sensor glucose readings.
(Scroll down from the 6-hour graph to reach the 12-hour graph)
12-Hour Trend Graph: The 12-hour trend graph shows your current sensor glucose reading and the last 12 hours of sensor glucose readings.
(Scroll down from the 12-hour graph to reach the 24-hour graph)
 **24-Hour Trend Graph:** The 24-hour trend graph shows your current sensor glucose reading and the last 24 hours of sensor glucose readings.

The receiver displays “LOW” when the most recent sensor glucose reading is less than 40 mg/dL and “HIGH” when the most recent sensor glucose reading is greater than 400 mg/dL.

Trend graph reading LOW



Trend graph reading HIGH

8.2 RATE OF CHANGE ARROWS

Your rate of change arrows add detail about the direction and speed of glucose change over the last 15-20 minutes.

The trend arrows show to the right of your current sensor glucose reading.

Do not overreact to the rate of change arrows. Consider recent insulin dosing, activity, food intake, your overall trend graph and your blood glucose value before taking action.

If there are missed communications between the sensor and receiver during the last 15-20 minutes, an arrow may not display.

This table shows the different trend arrows your receiver displays:

Rate of change arrow appears in upper right of trend graph

Trend Arrows

→	**Constant:** Your glucose is steady (not increasing/decreasing more than 1 mg/dL each minute). Your glucose could increase or decrease by up to 15 mg/dL in 15 minutes.
↗	**Slowly rising:** Your glucose is rising 1-2 mg/dL each minute. If it continued rising at this rate, your glucose could increase up to 30 mg/dL in 15 minutes.
↑	**Rising:** Your glucose is rising 2-3 mg/dL each minute. If it continued rising at this rate, your glucose could increase up to 45 mg/dL in 15 minutes.

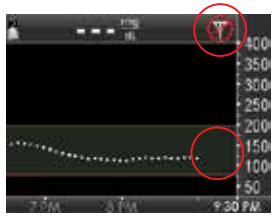
(continued on next page)

Trend Arrows (continued from page before)

↑↑	**Rapidly rising:** Your glucose is rising more than 3 mg/dL each minute. If it continued rising at this rate, your glucose could increase more than 45 mg/dL in 15 minutes.
↘	**Slowly falling:** Your glucose is falling 1-2 mg/dL each minute. If it continued falling at this rate, your glucose could decrease up to 30 mg/dL in 15 minutes.
↓	**Falling:** Your glucose is falling 2-3 mg/dL each minute. If it continued falling at this rate, your glucose could decrease up to 45 mg/dL in 15 minutes.
↓↓	**Rapidly falling:** Your glucose is falling more than 3 mg/dL each minute. If it continued falling at this rate, your glucose could decrease more than 45 mg/dL in 15 minutes.
No arrow	**No rate of change information:** The receiver cannot calculate how fast your glucose is rising or falling at this time.

Trend arrows show to the right of your sensor glucose reading. They tell you more about your glucose's speed and direction.

Trend arrows do not show when there are glucose data gaps (see Chapter 13, Section 13.4, System Glucose Error). If the glucose reading error symbol ???, the wait symbol, the out of range symbol, or the calibration needed symbol show at the top of the trend graph, the trend arrows will not show.



Trend graph with out of range symbol in upper right and glucose data gaps

If the trend arrow is missing, but you are concerned that your blood glucose level may be rising or falling, take a blood glucose measurement test on your blood glucose meter.

WARNING

Do not ignore symptoms of high and low glucose. If your sensor glucose alerts and readings do not match your symptoms, measure your blood glucose with a blood glucose meter even if your sensor is not reading in the high or low range. Solely relying on the sensor glucose alerts and readings for treatment decisions could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

8.3 GLUCOSE STATUS AREA SYMBOLS

The “status area” at the top of the trend graph may show any of the following status symbols during your sensor session. You will not get sensor glucose readings during the time a status symbol shows except during the regular 12-hour calibration prompt.

Status Symbols

Calibration Needed	This symbol means you need to enter a calibration. This prompt will show when it is time for your 12-hour calibration update or any other time an additional calibration is needed (see Chapter 7, Section 7.2, How to Calibrate).
Additional Startup Calibration Needed	This symbol means you need to enter one more blood glucose value in order to calibrate the system and start getting sensor glucose readings.

(continued on next page)

Status Symbols (continued from page before)

Glucose Reading Error	This symbol means the receiver does not understand the sensor signal but is likely to recover. This symbol is related to the sensor only. You should wait for more prompts and **do not enter** any blood glucose values when you see this symbol (see Chapter 13, Section 13.4, System Glucose Error for more information).
Out of Range	This symbol means the receiver and sensor/transmitter are not communicating. Make sure the receiver and sensor/transmitter are within 20 feet of each other without obstruction (see Chapter 1, Section 1.4, Transmitter Overview).
Wait 15 Minutes Calibration Error	This symbol means the sensor cannot calibrate right now. If you see this screen, enter at least one more calibration blood glucose value after about 10-15 minutes. If the sensor still cannot calibrate after that, the sensor needs to be removed and a new sensor needs to be inserted.
Wait 1 Hour Calibration Error	This symbol means the sensor is not calibrating correctly. If you see this screen, wait a minimum of one hour and then enter one more blood glucose value. If no readings display on the receiver after this, the sensor needs to be removed and a new sensor needs to be inserted.
Wait	This symbol means the receiver has detected a potential significant problem with the sensor signal and may result in a sensor failure. You should wait about 30 minutes for more prompts. Do not enter any blood glucose values when you see this symbol.

Status symbols show in the upper right of your trend graph.

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chapter nine

ALERTS, ALARM & PROFILES

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CHAPTER 9: ALERTS, ALARM & PROFILES

This chapter teaches you about your Dexcom G4 PLATINUM (Pediatric) CGM System's many alerts and alarm and how to set them.

9.1 SETTING YOUR ALERTS

9.1.1 DEFAULT ALERT/ALARM SETTINGS

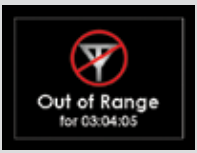
The following alerts and alarm are preset on your receiver.

Default Alert/Alarm Settings

What will I see on the receiver screen?	What does this mean?	What is the default setting?	How will the receiver notify me?	Will the receiver re-notify me?
	High Glucose Alert Your most recent sensor glucose reading is at or above the high alert setting.	On at 200 mg/dL	Vibrates 2 times and then vibrates/beeps 2 times every 5 minutes until confirmed or your glucose value drops below the alert level.	No, unless you have turned on the high alert snooze feature.

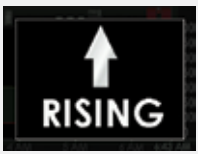
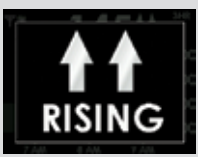
(continued on next page)

Default Alert/Alarm Settings (continued from page before)

What will I see on the receiver screen?	What does this mean?	What is the default setting?	How will the receiver notify me?	Will the receiver re-notify me?
	Low Glucose Alert Your most recent sensor glucose reading is at or below the low alert setting.	On at 80 mg/dL	Vibrates 3 times and then vibrates/beeps 3 times every 5 minutes until confirmed or your glucose value goes above the alert level.	No, unless you have turned on the low alert snooze feature.
	Low Glucose Alarm Your most recent sensor glucose reading is at or below 55 mg/dL	On	Vibrates 4 times and then vibrates/beeps 4 times every 5 minutes until confirmed or your glucose value goes above 55 mg/dL.	Yes, every 30 minutes after each confirmation until your blood glucose value comes back into range.
	**Out of Range Alert** The transmitter and receiver are not communicating to each other.	Off	The alert will not notify you. You must change the settings to receive this alert.	No

(continued on next page)

Default Alert/Alarm Settings (continued from page before)

What will I see on the receiver screen?	What does this mean?	What is the default setting?	How will the receiver notify me?	Will the receiver re-notify me?
 	**Rise/Fall Alert Single Arrow** Your glucose is rising/falling at or above a rate of 2 mg/dL/min (at least 30 mg/dL in 15 minutes).	Off	The alert will not notify you. You must change the settings to receive this alert.	No
 	**Rise/Fall Alert Double Arrow** Your glucose is rising/falling at or above a rate of 3 mg/dL/min (at least 45 mg/dL in 15 minutes).	Off	The alert will not notify you. You must change the settings to receive this alert.	No

This table describes the receiver alerts and alarm and explains how the receiver will notify you in the default setting.

Your receiver may alert you at other times you need to take action, such as low battery, failed sensor, etc. See Chapter 18, Appendix I, for a detailed list of these other alerts.

9.1.2 GLUCOSE ALERTS AND ALARM

WARNINGS

- In a pediatric clinical study, larger differences were observed between this CGM device and actual blood glucose values compared to those differences observed in the adult clinical study. Use your blood glucose meter for treatment decision.
- In a pediatric clinical study, a significant number of low glucose events were not detected by CGM. Do not rely solely on CGM alerts to detect low glucose.

The Dexcom G4 PLATINUM (Pediatric) System lets you create personal settings for how you want the receiver to tell you what is going on. The low and high glucose alerts tell you when your sensor glucose readings are outside your target glucose range. Rise and fall (rate of change) alerts let you know when your glucose levels are changing fast (see Chapter 9, Section 9.2, Advanced Alerts). The Dexcom G4 PLATINUM (Pediatric) System also has a 55 mg/dL low glucose alarm that cannot be changed or turned off. This safety feature tells you your glucose level may be dangerously low. You can set high and low glucose alerts to vibrate and beep. This feature can help during sleeping, driving, exercising or during meetings.

When you have both your high and low alerts turned on, a gray zone on your trend graph shows your target range.

Please select your alert settings in consultation with your healthcare professional. The sensor glucose readings may differ from your blood glucose measurement. If your sensor glucose readings are higher than your blood glucose, sometimes your low alert may not vibrate and/or beep when your blood glucose is actually low, depending on your alert profile setting. Selecting a higher level for the low alert setting will reduce the missed low

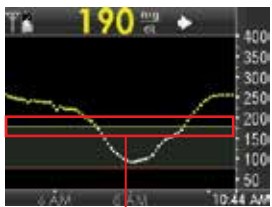
alerts but may cause more false alerts. It is important you discuss your alert settings with your healthcare professional.

9.1.2.1 HIGH GLUCOSE ALERT

When your sensor glucose readings are at or above your high alert level, this screen shows your high glucose alert level. Your receiver vibrates and/or beeps depending on your profile setting (see Chapter 9, Section 9.3, Alert Profiles). This level shows as a yellow line on the trend graph.

High glucose alert set at 200 mg/dL

The receiver continues to alert until you press the **SELECT** button to clear the alert or until your sensor glucose readings drop below your high glucose alert level. You can have the receiver re-alert after clearing the alert (to change your snooze settings see Chapter 9, Section 9.2, Advanced Alerts).



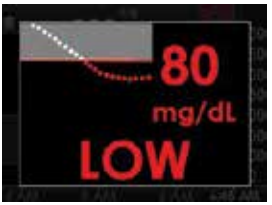
High glucose alert setting

9.1.2.2 LOW GLUCOSE ALERT

> **WARNING**
>
> In a pediatric clinical study, a significant number of low glucose events were not detected by CGM. Do not rely solely on CGM alerts to detect low glucose.

When your sensor glucose readings are at or below your low alert level, this screen shows your low glucose alert level. Your receiver vibrates and/or beeps depending on your profile setting. This level shows as a red line on the trend graph.

The receiver continues to alert until you press the **SELECT** button to clear the alert or until your sensor glucose readings rise above your low glucose alert level. You can have the receiver re-alert after clearing the alert (to change your snooze settings see Chapter 9, Section 9.2, Advanced Alerts).



Low glucose alert set at 80 mg/dL

Low glucose alert setting

9.1.2.3 LOW GLUCOSE ALARM

WARNING

In a pediatric clinical study, a significant number of low glucose events were not detected by CGM. Do not rely solely on CGM alerts to detect low glucose.

The Dexcom G4 PLATINUM (Pediatric) System also has a fixed low alarm at 55 mg/dL. This is different than your low glucose alert. You cannot change or turn off this alarm or its re-alarm settings.

- The receiver displays the low glucose alarm screen.
- Re-alarm: The receiver automatically alerts again 30 minutes after you press the **SELECT**

Low glucose alarm

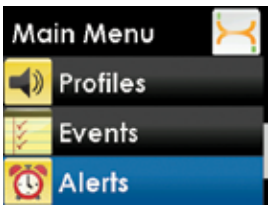
button to clear it, if your sensor glucose readings are still at or below 55 mg/dL.

- Your receiver does not alert if you have a sensor glucose reading outside your target range and you calibrated in the last 5 minutes.
- The receiver alerts if your sensor glucose reading stays outside your target range after five minutes.

9.1.3 GETTING TO THE ALERTS MENU

1. Press the **SELECT** button to turn on the receiver. The 3-hour trend graph shows.
2. Press the **SELECT** button to see the Main Menu.
3. From the Main Menu, press the **UP** or **DOWN** button to scroll to "Alerts," and press the **SELECT** button. The Alerts menu shows.

Trend graph



Main Menu,
Alerts highlighted

Alerts menu,
High Alert highlighted

9.1.4 HIGH AND LOW GLUCOSE ALERTS

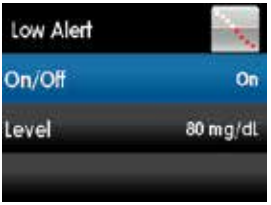
The steps for setting both the high alert and the low alert are the same.

The following steps show you how to change your high and low alert settings.

1. From the Alerts menu, press the **UP** or **DOWN** button to select "High Alert" or "Low Alert" and press the **SELECT** button.

Alerts menu,
Low Alert highlighted

2. Highlight “On/Off,” and then press the **SELECT** button to set this option. A check mark shows next to the current setting.



Low Alert menu, On/Off highlighted, On selected

3. Press the **LEFT** button to return to the last screen.
4. Press the **DOWN** button to highlight “Level.” The number that shows is your current glucose alert level.

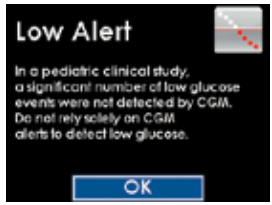
Low Alert menu, Level highlighted

5. To change this number, press the **SELECT** button, and then press the **UP** or **DOWN** button to select your glucose alert level.
   - Your high glucose alert value can be set between 120 and 400 mg/dL in 10 mg/dL steps.
   - Your low glucose alert value can be set between 60 and 100 mg/dL in 5 mg/dL steps.

Low Alert setting screen, 80 mg/dL selected

6. Press the **SELECT** button to confirm your alert level.

7. This screen appears when you set the low alert to remind you that your Dexcom G4 PLATINUM (Pediatric) System may not detect all low glucose events. Check with your blood glucose meter when or if you have signs and symptoms of low glucose. Press the **SELECT** button to confirm you have read and understand this message.



Low Alert warning screen

8. You will return to the Alerts menu when you finish.

9.2 ADVANCED ALERTS

Advanced alerts include the high and low snooze, rise and fall rate, and out of range alerts. All advanced alerts follow the following steps.

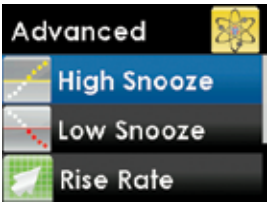
1. Press the **SELECT** button to turn on the receiver.
2. Press the **SELECT** button to enter the Main Menu.
3. Press the **UP** or **DOWN** button to highlight “Alerts,” and press the **SELECT** button.
4. From the Alerts menu, press the **UP** or **DOWN** button to select “Advanced,” and press the **SELECT** button.

Alerts menu, Advanced highlighted

9.2.1 SETTING A SNOOZE TIME FOR YOUR HIGH AND LOW GLUCOSE ALERTS

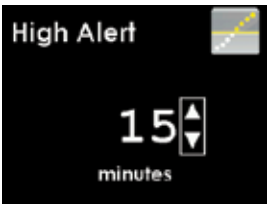
The snooze feature lets you delay your high and low glucose re-alerts. You have the option to set a snooze time for every 15 minutes for up to 5 hours.

1. Press the **UP** or **DOWN** button to highlight "High Snooze" or "Low Snooze" and press the **SELECT** button.



Advanced menu,
High Snooze highlighted

2. Press the **UP** or **DOWN** button to select the amount of time (in 15 minute steps) between the first alert and re-alerts. Press the **SELECT** button.
   - **If you set the amount of time to zero there will be no re-alerts**.
3. Press the **LEFT** button to return to the Alerts menu when you finish.



High Alert setting screen,
15 minutes selected

9.2.2 RISE AND FALL GLUCOSE RATE ALERTS

Rate alerts tell you when your glucose levels are rising (rise alert) or falling (fall alert) and by how much. You can choose for your receiver to alert when your sensor glucose reading is rising or falling 2 mg/dL or more per minute, or 3 mg/dL or more per minute.

Please select your alert settings in consultation with your healthcare professional. The sensor glucose readings may differ from your blood glucose measurement. If your sensor glucose readings are changing slower than your blood glucose is actually changing, sometimes your rise or fall glucose rate alerts may not vibrate and/or beep when your blood glucose is actually rising or falling. Selecting the 2 mg/dL level setting instead of the 3 mg/dL level setting will reduce the missed alerts but may cause more false alerts. It is important you discuss your alert settings with your healthcare professional.

If you set your fall rate to 2 mg/dL per minute and your sensor glucose readings fall at this rate or faster, the “FALLING single arrow” screen shows, and the receiver vibrates or beeps in line with your profile settings.

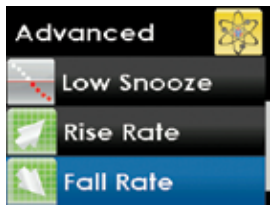
Fall alert

If you set your rise rate to 3 mg/dL per minute and your sensor glucose readings rise at this rate or faster, the “RISING double arrow” screen shows, and the receiver vibrates or beeps in line with your profile settings.

Rapid rise alert

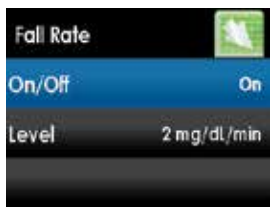
These steps show how to change your rise or fall rate alert settings.

1. Press the **UP** or **DOWN** button to choose “Rise Rate” or “Fall Rate,” and press the **SELECT** button.



Advanced menu, Fall Rate highlighted

2. Highlight “On/Off” and then press the **SELECT** button.



Fall Rate menu, On/Off highlighted

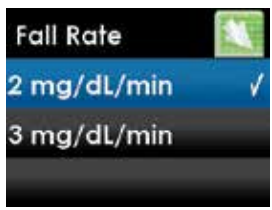
3. Press the **UP** or **DOWN** button to choose "On" or "Off." Then, press the **SELECT** button to select "On" or "Off."

Fall Rate menu,
On selected

4. Press the **LEFT** button to go back to the last screen. Highlight "Level" and then press the **SELECT** button.

Fall Rate menu,
Level highlighted

5. Choose "2 mg/dL/min" (2 mg/dL or more per minute) or "3 mg/dL/min" (3 mg/dL or more per minute). Press the **SELECT** button.



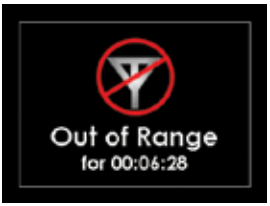
Fall Rate menu,
2 mg/dL/min selected

6. Press the **LEFT** button to return to the Alerts menu when you finish.

9.2.3 SETTING THE OUT OF RANGE ALERT

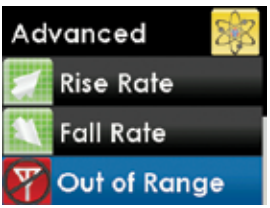
The out of range alert lets you know when the transmitter and receiver are not communicating with each other. Keep the transmitter and receiver within 20 feet of each other without obstruction. When the transmitter and receiver are too far apart, you will not get sensor glucose readings.

The out of range symbol in the upper right corner of the trend graph and the Out of Range alert screen show when the transmitter and receiver are not communicating. The amount of time out of range shows on the Out of Range alert screen. It will continue to re-alert until they are back in range.



Out of Range alert screen

1. Press the **UP** or **DOWN** button to choose “Out of Range,” and press the **SELECT** button.



Advanced menu, Out of Range highlighted

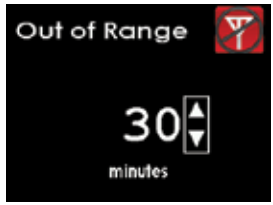
2. Press the **UP** or **DOWN** button to choose “On/Off.” Then, press the **SELECT** button to select “On.” If you do not want to get out of range alert press the **SELECT** button again to choose “Off.”

Out of Range menu, On/Off highlighted

3. Press the **UP** or **DOWN** button to choose “Time,” and press the **SELECT** button.

Out of Range menu, Time highlighted

4. Press the **UP** or **DOWN** button to choose the amount of time out of range after which the receiver will alert. Press the **SELECT** button.

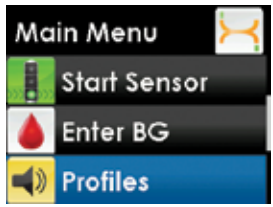


Out of Range setting screen, 30 minutes selected

5. Press the **LEFT** button to return to the Alerts menu when you finish.

9.3 ALERT PROFILES

The Dexcom G4 PLATINUM (Pediatric) System lets you set profiles to choose the way you want your alerts to act. This feature is found under the Profiles option on the Main Menu. You can set your profile to the sound pattern and volume that fits your needs.



Main Menu, Profiles highlighted

Your profile options are:
1. Vibrate
2. Soft
3. Normal
4. Attentive
5. HypoRepeat

For each profile option, the first alert is vibration only.

Regardless of which alert profile you chose, if you confirm the first vibrate alert, you will not get a sound alert.

When you choose your profile setting this setting applies to all alerts, alarm and prompts.

Within each profile setting, each alert has its own unique sound pattern, tone and volume level. This lets you to easily identify each alert and alarm and its meaning.

The fixed low alarm at 55 mg/dL cannot be turned off or adjusted.

The soft, normal, attentive and HypoRepeat profiles have the following alert sequence:

- The first alert is vibrate only.
- If the alert is not confirmed in five minutes, the system vibrates and beeps.
- If the alert is not confirmed in five more minutes, the system vibrates and beeps louder. This continues at the same volume every five minutes until confirmed.

For the HypoRepeat profile only:

- If the alert is confirmed and your sensor glucose readings continue to be at or below 55 mg/dL your system repeats the alert sequence in 30 minutes.

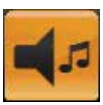
Press the **SELECT** button to confirm any alert.

9.3.1 ALERT PROFILE OPTIONS

Vibrate profile: when you want to silence the receiver and be alerted by vibration. The only exception to this is the fixed low alarm at 55 mg/dL, which alerts you as a vibration first, followed by beeps 5 minutes later if not confirmed.

Soft profile: when you need your alert to be less noticeable. This profile sets all the alerts and alarm to lower volume beeps.

Normal profile: the default profile when you receive your system. This profile sets all alerts and alarm to higher volume beeps.



Attentive profile: when you need your alert to be the most noticeable. This profile sets all the alerts and alarm to loud and highly distinctive melodies.

(continued on next page)

ALERT PROFILE OPTIONS (continued from page before)

"HypoRepeat" profile: very similar to the normal profile, but it continuously repeats the fixed low alarm every 5 seconds until your sensor glucose reading rises above 55 mg/dL or is confirmed. This profile can be helpful if you want extra alerts for severe low sensor glucose readings.

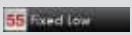
The "Try It" feature is found under the Profiles menu and lets you hear an example of each alert and alarm.

9.3.2 ALERT PROFILE DETAILS

PROFILE TYPE	VIBRATE	SOFT	NORMAL	ATTENTIVE	HYPOREPEAT
High Alert	2 long vibrates	2 long vibrates + 2 low beeps	2 long vibrates + 2 medium beeps	2 long vibrates + ascending melody	2 long vibrates + 2 medium beeps
Low Alert	3 short vibrates	3 short vibrates + 3 low beeps	3 short vibrates + 3 medium beeps	3 short vibrates + descending melody	3 short vibrates + 3 medium beeps
Rise Alert	2 long vibrates	2 long vibrates + 2 low beeps	2 long vibrates + 2 medium beeps	2 long vibrates + 1 short ascending melody	2 long vibrates + 2 medium beeps
Fall Alert	3 short vibrates	3 short vibrates + 3 low beeps	3 short vibrates + 3 medium beeps	3 short vibrates + 2 short descending melodies	3 short vibrates + 3 medium beeps

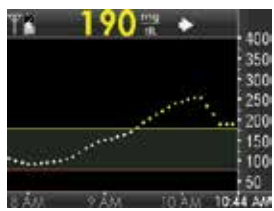
(continued on next page)

ALERT PROFILE DETAILS (continued from page before)

PROFILE TYPE	VIBRATE	SOFT	NORMAL	ATTENTIVE	HYPOREPEAT
Out of Range Alert	1 long vibrate	1 long vibrate + 1 low beep	1 long vibrate + 1 medium beep	1 long vibrate + 3 short repeating melodies	1 long vibrate + 1 medium beep
Fixed Low 	4 short vibrates + 4 medium tone beeps	4 short vibrates + 4 medium tone beeps	4 short vibrates + 4 medium tone beeps	4 short vibrates + 2 long descending melodies + pause + 4 low beeps	4 short vibrates + 4 low beeps + pause + repeat sequence
All Other Alerts	1 long vibrate	1 long vibrate + 1 low beep	1 long vibrate + 1 medium beep	1 long vibrate + 1 short melody	1 long vibrate + 1 medium beep

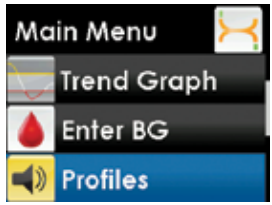
These steps show you how to select the profile you want.

1. Press the **SELECT** button to turn on the receiver. The 3-hour trend graph will show.



Trend graph

2. Press the **SELECT** button to see the Main Menu.
3. Press the **UP** or **DOWN** button to scroll to "Profiles," and press the **SELECT** button. The Profiles menu will show.



Main Menu,
Profiles highlighted

4. Press the **UP** or **DOWN** button to scroll to the profile you want to set, and press the **SELECT** button.

Profiles menu,
Vibrate highlighted

5. Press the **LEFT** button to return to the Main Menu when you finish.

10

chapter ten

EVENTS

10

CHAPTER 10: EVENTS

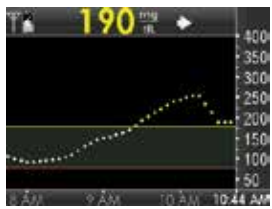
The Events feature lets you record information that may help you and your healthcare professionals better understand your glucose patterns and trends. You can enter details about carbohydrates, insulin, exercise, and health issues. You can view these events with your trends and patterns using the Dexcom STUDIO software.

10.1 EVENTS

Event markers can be downloaded and viewed in the Dexcom STUDIO software but cannot be viewed on your receiver.

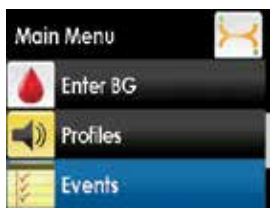
10.1.1 SELECTING AN EVENT

1. Press the **SELECT** button to turn on the receiver. The 3-hour trend graph will show.
2. Press the **SELECT** button to see the Main Menu.



Trend graph

3. Press the **UP** or **DOWN** button to scroll to "Events," and press the **SELECT** button. The Events menu will show.



Main Menu,
Events highlighted

4. Press the **UP** or **DOWN** button to choose the event you want: “Carbs,” “Insulin,” “Exercise” or “Health.” Press the **SELECT** button.

Events menu,
Carbs highlighted

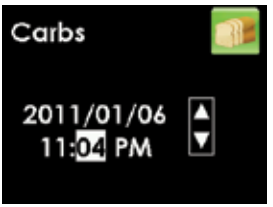
10.1.2 SETTING THE DATE AND TIME FOR AN EVENT

When you enter an event, you must check that the date and time for that event are correct. The default is the current date and time stored in the receiver. The date format is YYYY/MM/DD.

If you change the date or time for any event, it only applies to that event and will not change the current date and time in your receiver.

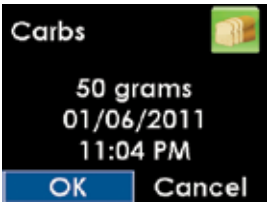
To change the date and time for an event:

1. Press the **RIGHT** button to highlight each value in the date and time.
2. Press the **UP** or **DOWN** button to make any changes, and then press the **RIGHT** button to move to the next value.
3. Press the **SELECT** button after choosing “AM” or “PM.”



Carbs setting screen,
minutes highlighted

4. Press the **SELECT** button to confirm the entry.

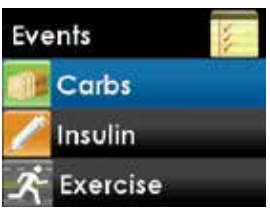


Carbs setting screen, OK highlighted

10.1.3 CARBOHYDRATES

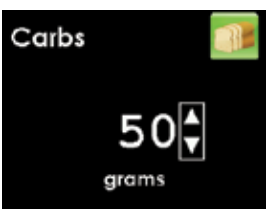
The Carbs event lets you enter the amount of carbohydrates you have taken, up to 250 grams.

1. From the Events menu press the **UP** or **DOWN** button to choose “Carbs,” and press the **SELECT** button.



Events menu, Carbs highlighted

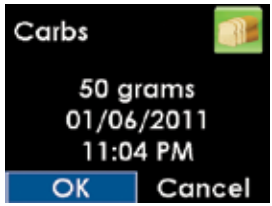
2. Press the **UP** or **DOWN** button to enter your carb amount (0-250 grams), and press the **SELECT** button.
   - The number that shows on this screen is the last number you entered or the default amount of 50 grams.



Carbs setting screen, 50 grams selected

3. Check that the date and time for this entry are correct. Press the **SELECT** button to confirm.

4. Press the **LEFT** or **RIGHT** button to choose either “OK” to confirm or “Cancel” to discard this entry, and then press the **SELECT** button. You will return to the Events menu.



Carbs setting screen, OK highlighted

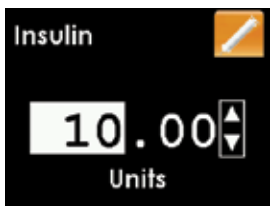
10.1.4 INSULIN

The Insulin event lets you enter the amount of insulin you have taken, up to 250 units. You can only enter an insulin amount, not the type of insulin.

1. From the Events menu press the **UP** or **DOWN** button to choose “Insulin,” and press the **SELECT** button.

Events menu, Insulin highlighted

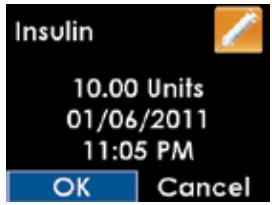
2. Press the **UP** or **DOWN** button to enter your insulin amount (0-250 units), and press the **SELECT** button.
   - The number that shows on this screen is the last number you entered or the default amount of 10 units.



Insulin setting screen, 10 units highlighted

3. Check that the date and time for this entry are correct. Press the **SELECT** button to confirm.

4. Press the **LEFT** or **RIGHT** button to choose either “OK” to confirm this entry or “Cancel” to discard this entry, and then press the **SELECT** button. You will return to the Events menu.

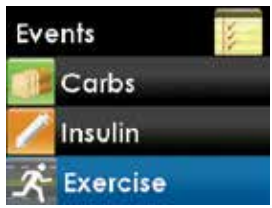


Insulin setting screen, OK highlighted

10.1.5 EXERCISE

The Exercise event lets you enter intensity (light, medium, or heavy) and duration (up to 360 minutes).

1. From the Events menu press the **UP** or **DOWN** button to choose “Exercise,” and press the **SELECT** button.

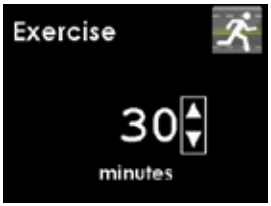


Events menu, Exercise highlighted

2. Press the **UP** or **DOWN** button to choose your exercise intensity level, and press the **SELECT** button.

Exercise Type menu, Light highlighted

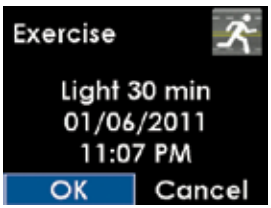
3. Press the **UP** or **DOWN** button to enter your exercise duration (0-360 minutes), and press the **SELECT** button.
   - The number that shows on this screen is the default amount of 30 minutes.



Exercise setting screen, 30 minutes selected

4. Check that the date and time for this entry are correct. Press the **SELECT** button to confirm.

5. Press the **LEFT** or **RIGHT** button to choose either “OK” to confirm this entry or “Cancel” to discard this entry, and then press the **SELECT** button. You will return to the Events menu.



Exercise setting screen, OK highlighted

10.1.6 HEALTH

The Health event lets you enter episodes of illness, stress, high symptoms, low symptoms, cycle (menstrual) or alcohol consumption.

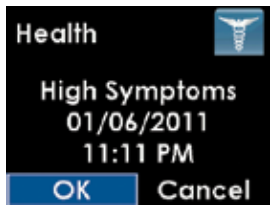
1. From the Events menu press the **UP** or **DOWN** button to choose “Health,” and press the **SELECT** button.

Events menu, Health highlighted

2. Press the **UP** or **DOWN** button to choose your health event, and press the **SELECT** button.

Health menu, Illness highlighted

3. Check that the date and time for this entry are correct. Press the **SELECT** button to confirm.
4. Press the **LEFT** or **RIGHT** button to choose either “OK” to confirm this entry or “Cancel” to discard this entry, and then press the **SELECT** button. You will return to the Events menu.



Health setting screen, OK highlighted

10.2 DEXCOM STUDIO SOFTWARE

The Dexcom STUDIO software is optional. This software lets you view trends, track patterns and create custom charts to display your glucose trends.

You can change the date ranges to view long- or short-term patterns and trends. You can use data from current and older downloads and save or print files for you and your healthcare professionals to review.

For system requirements and more information, see the Dexcom website (www.dexcom.com) or the Dexcom STUDIO Software User’s Guide.

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chapter eleven

ENDING A SENSOR SESSION

11

CHAPTER 11: ENDING A SENSOR SESSION

PRECAUTION

Do not discard your transmitter. It is reusable. The same transmitter is used for each session until you have reached the end of the transmitter battery life.

Your sensor gives you sensor glucose readings for up to seven days. The performance of a sensor has not been tested beyond seven days.

Information for the end of a sensor session:

- Do not remove the transmitter from the sensor pod while the pod is attached to your skin.
- Consult your local waste management authorities for instructions to dispose of blood contacting parts (sensor and applicator).
- In some cases, your sensor session may end before you have finished a full 7-day period. If this happens, see Chapter 13, Section 13.6, Sensor Shut-Off Troubleshooting.
- **Glucose alerts and alarm do not work after the sensor session ends.**

11.1 AUTOMATIC SENSOR SHUT-OFF

The receiver tells you how much time you have left until your sensor session is complete. The Replace Sensor screen shows at 6 hours, 2 hours and 30 minutes before your 7-day sensor session ends.

6-hour Replace Sensor

2-hour Replace Sensor

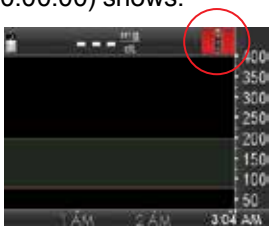
30-minute Replace Sensor

Replace Sensor
end of session

You can set these alerts with the profiles setting (see Chapter 9, Section 9.3.2, Alert Profile Details, “All Other Alerts”). After the 6-hour, 2-hour, and 30-minute reminders, you continue to receive sensor glucose readings. Press **SELECT** to clear these screens. You must remove your sensor after the Replace Sensor Now screen (00:00:00) shows.

Sensor glucose readings do not show on the receiver after your sensor session ends. The trend graphs show that the sensor session has ended with a red stoplight symbol at the top.

You must remove your sensor and insert a new sensor.



Trend graph with
red stoplight in upper right

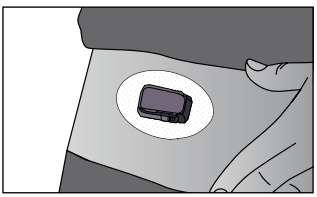
11.2 REMOVING A SENSOR

WARNING

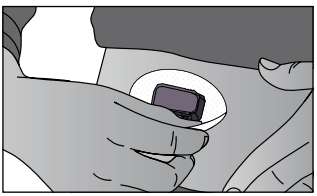
Do not ignore sensor fractures. Sensors may fracture on rare occasions. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the insertion site. If you experience a broken sensor, please report this to our Technical Support department at **1.877.339.2664 or 1.858.200.0200 24 hours a day, 7 days a week**.

When you remove the sensor, make sure to pull out the sensor pod while the transmitter is still attached.

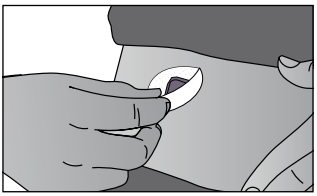
1. Gently peel up the sensor pod adhesive patch from your skin. This will pull out your sensor.



Keep the transmitter in the sensor pod



Peel up the sensor pod adhesive patch



Completely remove the adhesive patch

11.3 TRANSMITTER REMOVAL

PRECAUTION

Do not discard your transmitter. It is reusable. The same transmitter is used for each session until you have reached the end of the transmitter battery life.

Do not remove the transmitter while the sensor pod is still attached to the body.

After the sensor pod is off your body, you must remove the transmitter to reuse it. Use either of these two transmitter removal methods:

Method 1

The safety lock that you removed from the applicator (see Chapter 6, Section 6.4, Placing the Sensor), can be used as a tool to remove the transmitter.

1. Place the sensor pod/transmitter on a flat surface.
2. Hold the rounded edge of the safety lock.
3. Make sure the jagged edge of the safety lock is facing down, with the arrow pointing up, as shown:

Safety lock

Transmitter with safety lock snapped in

Method 2

Use your fingers to spread out the tabs at the back of the sensor pod (end closest to the sensor pod tab wings). The transmitter will “pop” out of the sensor pod.

chapter twelve

TAKING CARE OF YOUR DEXCOM G4 PLATINUM (PEDIATRIC) SYSTEM

12

CHAPTER 12: TAKING CARE OF YOUR DEXCOM G4 PLATINUM (PEDIATRIC) SYSTEM

12.1 MAINTENANCE

Transmitter

- Wipe the outside of the transmitter with a damp cloth or isopropyl alcohol wipe between uses.
- Keep the transmitter protected when not in use.

Receiver

- Do not spill fluid on the receiver or submerge the receiver in liquid.
- Keep the receiver in its carrying case or otherwise protected.
- Charge the receiver when the battery gets low.
- **Keep the micro USB port cover closed to help prevent fluid from getting inside the receiver.**

Accessories

- Insert cables only as directed. Do not force cables in place.
- Look at cables for signs of wear and tear.
- Only use Dexcom-supplied parts (including cables and chargers). Use of non-Dexcom supplied parts may affect safety and performance.

There is no repair service available for your Dexcom G4 PLATINUM (Pediatric) CGM System. If you experience problems with your system contact Dexcom Technical Support (see Chapter 15, User Assistance).

12.2 STORAGE

Sensor

- Keep the sensor in its sterile packaging until you are ready to use it.
- Do not insert sensors past the expiration date. The expiration date format is YYYY-MM-DD. Insert sensors on or before the end of the

calendar day printed on the sensor package label.

- Store at temperatures between 36° F - 77° F. Storing outside this temperature may result in reduced sensor response to glucose and may cause inaccurate CGM readings. You may store your sensors in the refrigerator if it is within this temperature range. Sensors should not be stored in a freezer.
- Store at humidity levels between 15% - 85% relative humidity.

Transmitter

- Keep the transmitter protected when not in use.
- Store at temperatures between 32° F - 113° F.
- Store at humidity levels between 10% - 95% relative humidity.

Receiver

- Keep the receiver protected when not in use.
- Fully charge the battery before storing for over 3 months.
- Store at temperatures between 32° F - 113° F.
- Store at humidity levels between 10% - 95% relative humidity.

12.3 PRODUCT DISPOSAL

Consult your local waste management authorities for instructions to dispose of devices containing electronic waste (transmitter and receiver) and blood contacting parts (sensor and applicator).

chapter thirteen

TROUBLESHOOTING

13

CHAPTER 13: TROUBLESHOOTING

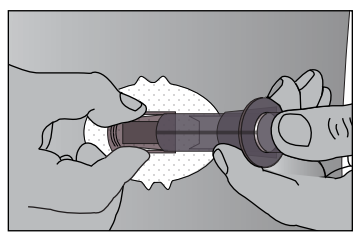
This chapter provides helpful tips and instructions to fix issues you may have while using your Dexcom G4 PLATINUM (Pediatric) CGM System.

If any of the troubleshooting steps in this chapter do not fix your issue, contact Dexcom Technical Support (see Chapter 15, User Assistance).

13.1 SENSOR INSERTION TROUBLESHOOTING

Sensor insertion difficulties

- **I am having trouble taking out the safety lock:**
  - Make sure to pull the safety lock straight out away from your body. Use the arrows on the safety lock as a guide.
- **I am not able to pull the collar up:**
  - Make sure the white plunger is completely pressed down before pulling the collar up.
  - Use force when pulling the collar up.
- **I am not able to remove the applicator barrel from the sensor pod:**
  - Make sure the collar is pulled all the way up. When pulling the collar up you should hear 2 “clicks.” You may need to use extra force to pull the collar as close to the top of the applicator as possible.
  - Make sure the transmitter latch is flat against the adhesive on your body before squeezing the release tabs.



Release the applicator barrel

  - Use force when squeezing the ribbed release tabs on the sides of the sensor pod.
  - Lift the applicator in a curving movement away from your body.

- **I am not able to remove the transmitter latch:**
  - Hold the sensor pod with one hand and twist the transmitter latch with the other hand to remove it.
  - Do not try to snap it straight off.

Sensor pod is not sticking long enough

- Make sure your skin is clean, clear of any cream or lotion, and completely dry before you insert the sensor.
- Shave your skin before you insert the sensor if hair is preventing the sensor pod from sticking.
- You may use medical tape (such as Blenderm, Tegaderm, IV 3000, 3M tape) over the white adhesive patch of the sensor pod, but do not place the tape over the transmitter or the plastic parts of the sensor pod.

13.2 CALIBRATION TROUBLESHOOTING

Calibration prompts may show during your sensor session. Review the following troubleshooting tips for calibration.

- Do not calibrate if the out of range symbol shows in the status area.
- Do not calibrate if the glucose reading error symbol shows in the status area.
- Do not calibrate if your blood glucose value is below 40 or above 400 mg/dL.
- Before you take a blood glucose value for calibration, wash your hands, make sure your glucose test strips have been stored properly and are not expired and make sure that your meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions that came with your meter or test strips.
- Make sure you have not taken any medications containing acetaminophen (such as Tylenol).

- See Chapter 7, Calibrating Your Dexcom G4 PLATINUM (Pediatric) System, for further information.

13.2.1 TYPES OF CALIBRATION PROMPTS

This section describes the three calibration symbols. The next section describes what to do when you see one of these symbols.

Startup calibration prompt

This prompt means the receiver's 2-hour startup period is complete. You need to enter two blood glucose values to calibrate the system.

The receiver shows the 2-hour startup calibration prompt screen every 15 minutes until the receiver accepts the blood glucose values.

Startup calibration prompt

Additional startup calibration prompt

This prompt means you need to enter one more blood glucose value to calibrate the system.

The receiver shows the additional startup calibration prompt screen every 15 minutes until the receiver accepts the blood glucose value.

Additional startup calibration prompt

Calibration prompt

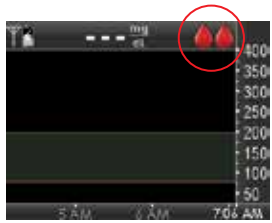
This prompt means you need to enter one blood glucose value. It shows when it is time for your 12-hour calibration update or any other time you need to calibrate.

The receiver shows this prompt screen every 15 minutes until the receiver accepts the blood glucose value.

Calibration prompt

13.2.2 WHAT TO DO FOR CALIBRATION PROMPTS

1. When you see a calibration prompt, press the **SELECT** button to clear the prompt.
2. Check the status area at the top of the screen.
   a. If the startup calibration symbol shows, take 2 more blood glucose values and enter them into your receiver.
   b. If the additional startup calibration symbol shows, take 1 more blood glucose value and enter it into your receiver.
   c. If the calibration needed symbol shows, take 1 more blood glucose value and enter it into your receiver.



Prompt in status area

13.3 CALIBRATION ERROR TROUBLESHOOTING

This screen means you recently entered a calibration blood glucose value, and the sensor is having trouble calibrating. If you press the **SELECT** button to clear this screen, this symbol shows in the status area.

Wait 15 minutes calibration error screen

If you see this screen, wait 15 minutes and then enter 1 more calibration blood glucose value. Wait 15 more minutes. If this error screen still shows, enter 1 more blood glucose value. Wait another 15 minutes. If this error screen still shows, the sensor needs to be replaced.

This screen also means you recently entered a calibration blood glucose value and the sensor is having trouble calibrating. If you press the

SELECT button to clear the screen, this symbol shows in the status area.

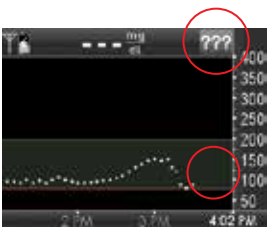
If you see this screen, wait at least 1 hour and then enter 1 more calibration blood glucose value. Wait 15 minutes. If this error screen still shows, enter 1 more blood glucose value. Wait another 15 minutes. If this error screen still shows, the sensor needs to be replaced.

Wait 1 hour calibration error screen

13.4 SYSTEM GLUCOSE ERROR

The system may tell you that it cannot provide a sensor glucose reading. When this happens you will see either the glucose reading error symbol ??? or the wait symbol in the status area. These symbols mean the receiver does not understand the sensor signal temporarily. These symbols are related to the sensor only.

Wait for more prompts, and **do not enter** any blood glucose values when you see these symbols. The system will not use a blood glucose value for calibration when these symbols show (see Chapter 8, Section 8.3, Glucose Status Area Symbols).



No glucose data (???)

Often, the system can correct the problem and continue providing sensor glucose readings. If it has been at least 3 hours since your last sensor glucose reading, contact Technical Support (see Chapter 15, User Assistance).

If you see these system glucose error symbols often, follow these troubleshooting tips before inserting another sensor:

- Make sure your sensor is not expired.

No glucose data ( )

- Make sure your sensor pod is not dislodged or peeling up.
- Make sure your transmitter is snapped in completely.
- Make sure nothing is rubbing the sensor pod (i.e. clothing, seat belts, etc.).
- Make sure you selected a good insertion site (see Chapter 6, Section 6.3, Choosing an Insertion Site).
- Make sure your insertion site is clean and dry before sensor insertion.
- Wipe the bottom of the transmitter with a damp cloth or isopropyl alcohol wipe. Place the transmitter on a clean, dry cloth and air dry for 2-3 minutes.

13.5 SENSOR INACCURACIES

Inaccuracies are usually related to your sensor only and not your receiver or transmitter. Your sensor glucose readings are meant to be used for trending purposes only. Your blood glucose meter and sensor measure your glucose from two different types of body fluids: blood and interstitial fluid. Therefore, your readings from your blood glucose meter readings and sensor may not match.

WARNINGS

- In a pediatric clinical study, larger differences were observed between this CGM device and actual blood glucose values compared to those differences observed in the adult clinical study. Use your blood glucose meter for treatment decision.
- In a pediatric clinical study, a significant number of low glucose events were not detected by CGM. Do not rely solely on CGM alerts to detect low glucose.
- Do calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate and glucose alerts to become unreliable. This could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

PRECAUTION

To calibrate the system, do enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Do not enter sensor glucose readings for calibration. Entering incorrect blood glucose values, blood glucose values obtained more than 5 minutes before entry, or sensor glucose readings might affect sensor accuracy and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

If the difference between your sensor glucose reading and blood glucose value is greater than 20% of the blood glucose value for sensor glucose readings > 80 mg/dL or greater than 20 points for sensor glucose readings < 80 mg/dL, wash your hands and take another blood glucose measurement. If the difference between this second blood glucose measurement and the sensor is still greater than 20% for sensor glucose readings > 80 mg/dL or greater than 20 points for sensor glucose readings < 80 mg/dL, recalibrate your sensor using the second blood glucose value. The sensor glucose reading will correct over the next 15 minutes. If you see differences between your sensor glucose readings and blood glucose values outside of this acceptable range, follow these troubleshooting tips before inserting another sensor:

- Make sure your sensor is not expired.
- Make sure you do not calibrate when the or is shown.
- Do not use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration as alternative site readings may be different than those from a blood glucose value. Use a blood glucose value only from your fingers for calibration.
- Use only blood glucose values between 40-400 mg/dL for calibration. If one or more of your values is outside of this range, the receiver will not calibrate.
- Use the same meter you routinely use to measure your blood glucose to calibrate. Do not switch your meter in the middle of a sensor session. Blood glucose meter and strip accuracy vary between blood glucose meter brands.
- Before taking a blood glucose measurement for calibration, wash your hands, make sure your glucose test strips have been stored properly and are not expired and make sure that your meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions provided with your meter or test strips.
- Make sure you are using your blood glucose meter following the

manufacturer's instructions to get accurate blood glucose values for calibration.

- Make sure you have not taken any medications containing acetaminophen (such as Tylenol) to ensure you are getting accurate blood glucose values for calibration.

13.6 SENSOR SHUT-OFF TROUBLESHOOTING

In some cases your sensor session may stop or need to be stopped before the end of a full 7-day period. You must remove your sensor.

13.6.1 EARLY SENSOR SHUT-OFF – SENSOR FAILURE

The receiver may detect issues with your sensor where it cannot determine your sensor glucose reading. The sensor session ends and the receiver shows the "Sensor Failed" screen. If you see this screen, it means your CGM session has ended. Press the **SELECT** button to clear this screen.

Sensor Failed screen

Remove your sensor and insert a new sensor.

To help improve future sensor performance:

- Make sure your sensor is not expired.
- Make sure your transmitter is snapped in.
- Make sure your sensor pod is not dislodged or peeling up.
- Make sure nothing is rubbing the sensor pod (i.e., clothing, seat belts, etc.).
- Make sure you have selected a good insertion site (see Chapter 6, Section 6.3, Choosing an Insertion Site).
- Make sure your insertion site is clean and dry prior to sensor insertion.

13.6.2 MANUAL SENSOR SHUT-OFF – “STOP SENSOR”

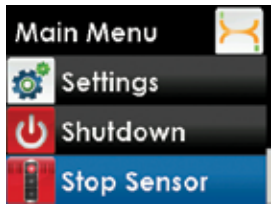
There may be times that you will want to stop your sensor session before the end of the seven days. Some of these times may include removing the sensor early due to:

- Calibration issues that cannot be resolved
- ??? symbol that does not resolve
- Sensor adhesion issues
- Lifestyle needs

When you are in an active sensor session, you will see the “Stop Sensor” option but not the “Start Sensor” option on the Main Menu.

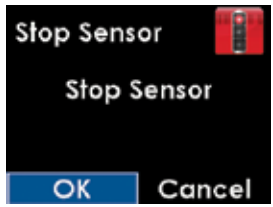
When you are not in an active sensor session, you will see the “Start Sensor” option but not the “Stop Sensor” option on the Main Menu.

Stop your sensor session if you remove your sensor before the end of the full 7 day period.



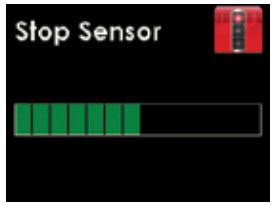
Main Menu,
Stop Sensor highlighted

1. To end your sensor session, select “Stop Sensor” from the Main Menu.
2. Press the **SELECT** button with “OK” highlighted to confirm.



Stop Sensor screen,
OK highlighted

3. The Stop Sensor “thinking” screen will show to let you know the sensor session is stopping.



Stop Sensor “thinking” screen

4. Once the session has stopped, a red stoplight symbol ( ) shows in the upper right of the trend graph.

Trend graph with red stoplight in upper right

13.7 SHARE PAIRING ERROR TROUBLESHOOTING

This screen means you recently turned Share “On,” and your receiver is having trouble connecting with your iPhone® or iPod touch®. If you press the “OK” button to clear this screen, you will be taken back to the Share menu and Share will be turned “Off.” Turn Share “On” to try pairing again. For more information on how to troubleshoot your Dexcom Share System, refer to the Dexcom Share User Manual.

Share unsuccessful pairing prompt

If you are not using the Share feature, you should leave Share turned “Off.”

13.8 BATTERY AND CHARGER TROUBLESHOOTING

Only use the Dexcom cable and battery charger to charge your receiver.

A full charge can take up to 5 hours and will last about 3 days, depending on how often you turn on your receiver, use the alerts, and enter events.

If your receiver does not show the battery charging symbol when plugged into the charger, make sure that both ends of the USB cable are fully inserted into the receiver port and wall charger or computer.

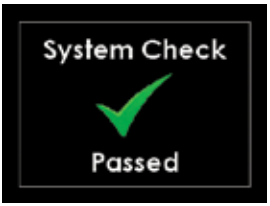
If your battery drains and is not charged for a few weeks it may not turn on. If your receiver does not turn on, first try to charge it (see Chapter 4, Section 4.1, Charging Your Receiver Battery). If your receiver still does not turn on you may need to reset the receiver:

1. Connect the receiver to the charger before resetting.
2. Insert the end of a paperclip into the small circular hole on the back of the receiver and push down. The receiver will vibrate and show the thinking screen.
3. Charge your receiver.
4. You may need to reset the time and date (see Chapter 4, Section 4.1, Charging Your Receiver Battery and Chapter 5, Section 5.2, The Settings Menu).

13.9 RECEIVER AND TRANSMITTER COMMUNICATION TROUBLESHOOTING

13.9.1 SYSTEM RECOVERY CHECK

This screen means the system found an error that it was able to fix. Press the **SELECT** button to clear this display, and continue your sensor session.



System Check screen

13.9.2 RECEIVER ERROR CODE

This screen shows an error code that means the receiver may not be working properly. Write down the error code and contact Dexcom Technical Support (see Chapter 15, User Assistance). Continue to check your blood glucose value using your blood glucose meter.

No alert sound or vibration will warn you that you are no longer getting sensor glucose readings.

Receiver Error Code screen

13.9.3 TRANSMITTER LOW BATTERY

This screen shows when the transmitter nears the end of its battery life (see Chapter 1, Section 1.4, Transmitter Overview). It will first show when there is about 1 week of battery life left. When the transmitter battery drains low enough, the transmitter and receiver will stop communicating. Replace your transmitter as soon as possible after you see this screen. Contact Dexcom Sales Support (see Chapter 15, User Assistance) to order a new transmitter.

Transmitter Low Battery screen

13.9.4 TRANSMITTER FAILED

This screen means that the transmitter is not working. If you get this alert during a sensor session, your sensor session automatically stops. Contact Dexcom Technical Support (see Chapter 15, User Assistance). Continue to check your blood glucose value using your blood glucose meter.

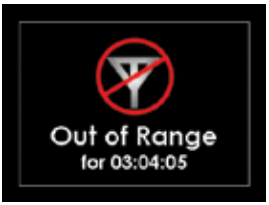
Transmitter Failed screen

13.10 OUT OF RANGE/NO ANTENNA

PRECAUTION

Avoid separating the transmitter and receiver by more than 20 feet. The transmission range from the transmitter to the receiver is up to 20 feet without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc. Types of obstruction differ and have not been tested. If your transmitter and receiver are farther than 20 feet apart or are separated by an obstruction, they might not communicate or the communication distance may be shorter and result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

This screen means your receiver and transmitter are not communicating and you are not getting sensor glucose readings.



Out of Range alert screen

- Your receiver and transmitter only communicate when you are in an active sensor session.
- Each time you start a new sensor session, wait 10 minutes for your receiver and transmitter to start communicating.
- You may sometimes experience loss of communication for 10 minutes at a time. This is normal.
- If you see the out of range symbol in the status area for more than 10 minutes, move your receiver and transmitter within 20 feet of each other without obstruction. Wait 10 minutes and communication should be restored.
- You must enter your transmitter ID correctly into your receiver to receive sensor glucose readings (see Chapter 5, Section 5.2, The Settings Menu). Make sure you have removed your sensor and stopped your sensor session before checking or changing your transmitter ID. “Transmitter ID” will not appear as an option on the Settings menu during a sensor session.

If you are still having trouble getting system readings, contact Dexcom Technical Support (see Chapter 15, User Assistance).

13.11 ALERTS ARE NOT WORKING

1. Make sure you have not turned off the sound and/or vibrations for the alerts. Chapter 9, Section 9.1, Setting Your Alerts explains how to change these alert options.
2. Check that you have turned on and set the level for your advanced alerts (see Chapter 9, Section 9.2, Advanced Alerts).
3. Remember, the first alert is vibrate only. See Chapter 18, Appendix

I, Receiver Alerts, Alarm and Prompts sequence tables for how the alerts, alarm and prompts work.

If your receiver gets wet or is dropped, make sure the speaker and vibrations still work. You can do this with the Try It option in the Profiles menu (see Chapter 9, Section 9.3.1, Alert Profile Options).

chapter fourteen

TECHNICAL INFORMATION

CHAPTER 14: TECHNICAL INFORMATION

14.1 DEVICE PERFORMANCE CHARACTERISTICS

NOTE: We recommend that you review the information in this chapter with your healthcare professional to understand how well the Dexcom G4 PLATINUM (Pediatric) System performs.

The Dexcom G4 PLATINUM (Pediatric) System (the System) uses a glucose sensor to continuously measure and monitor your glucose levels. The sensor is "calibrated" using a commercially available blood glucose meter; and once calibrated the System reports glucose readings up to every 5 minutes. The System was evaluated in a clinical study in which System readings were compared to blood glucose values to assess its performance and how well the System readings compare to a laboratory test method that measures blood glucose values. Additionally, patients performed self-monitoring blood glucose meter tests at home to assess the System performance in a real use environment.

Although the performance characteristics of the System are presented here, there is no commonly accepted statistical approach for capturing performance of continuous glucose monitors (CGMs), such as the Dexcom G4 PLATINUM (Pediatric) System.

Clinical Study Overview

The System performance for children and adolescents was evaluated in an observational prospective clinical study; 176 subjects age 2 to 17 were enrolled, with 16% of subjects younger than 6-years old. All subjects had Type 1 or Type 2 diabetes mellitus and required insulin or oral medication to manage their diabetes. About 99% of subjects had Type 1 diabetes and 1% had Type 2 diabetes. Sensors were inserted in either the abdomen or upper buttocks. Performance was similar between the two insertion sites. Subject's glucose levels were not intentionally manipulated during this study, so there are fewer data samples in the low and high glucose ranges than in the adult clinical

study (72 patients, age 18 and older).

Subjects used the System for seven days. All subjects wore 2 sensors. Sensors were calibrated approximately once every 12 hours, using the self-monitoring blood glucose (SMBG) meter values obtained from a LifeScan® OneTouch® Verio® IQ meter. The adult clinical study used the LifeScan® OneTouch® Ultra® 2 meter.

All subjects were evaluated in a controlled clinic environment on Day 1, Day 4 or Day 7 of the 7 day wear period. While using the System in the clinic, all subjects provided at least two fingerstick measurements per hour, and subjects ages 6-17 also provided venous blood for comparison to a reliable laboratory method, the Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer. This instrument is referred to as the "YSI." Readings from the System were reported every 5 minutes and paired with YSI values collected every 15 minutes in order to characterize how well the System readings agreed with laboratory standard blood glucose results. The System performance was also paired with the comparative LifeScan OneTouch Verio IQ meter results, referred to as the "SMBG." The remainder of the study took place at home where subjects took a minimum of 7 fingersticks per day.

Agreement Relative to YSI

Agreement between the System and blood glucose values is characterized using paired System and YSI values. The System and YSI results were compared by pairing the YSI blood glucose value to a System glucose reading that occurred immediately after the YSI was collected.

The agreement of the System to blood glucose value was assessed by calculating the percentage of System readings that were within 15%, 20%, 30%, 40% and greater than 40% of the YSI values. For readings less than or equal to 80 mg/dL (4.4 mmol/L) the absolute difference in mg/dL (mmol/L) between the two glucose results was calculated. For values greater than 80 mg/dL (4.4 mmol/L) the absolute percent difference (%) from the YSI values was calculated. The percentages of total readings within 15 mg/dL (0.8 mmol/L) or 15%, 20 mg/dL (1.1

mmol/L) or 20%, 30 mg/dL (1.7 mmol/L) or 30%, 40 mg/dL (2.2 mmol/L) or 40% or greater than 40 mg/dL (2.2 mmol/L) or 40% were then calculated in Table 1-A (pediatric study) and Table 1-B (adult study).

Table 1-A. System Agreement to YSI within CGM Glucose Ranges (Pediatric Study)

CGM Glucose Range mg/dL (mmol/L)	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent within 40/40% YSI	Percent Greater than 40/40% YSI
Overall	2922	55%	68%	85%	93%	7%
40-60 (2.2-3.3)	19	63%	74%	79%	79%	21%
61-80 (3.4-4.4)	76	61%	82%	92%	96%	4%
81-180 (4.5-10.0)	1155	56%	69%	84%	94%	6%
181-300 (10.1-16.7)	1380	55%	68%	85%	93%	7%
301-350 (16.7-19.4)	206	48%	62%	80%	89%	11%
351-400 (19.4-22.2)	86	48%	61%	79%	88%	12%

NOTE: CGM readings are within 40-400 mg/dL (2.2-22.2 mmol/L), inclusive.

Table 1-B. System Agreement to YSI within CGM Glucose Ranges (Adult Study)

CGM Glucose Range mg/dL (mmol/L)	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent within 40/40% YSI	Percent Greater than 40/40% YSI
Overall	9152	71%	82%	92%	97%	3%
40-60 (2.2-3.3)	512	67%	78%	88%	94%	6%
61-80 (3.4-4.4)	781	73%	85%	94%	98%	2%
81-180 (4.5-10.0)	3853	67%	78%	91%	97%	3%
181-300 (10.1-16.7)	2784	72%	84%	93%	96%	4%
301-350 (16.7-19.4)	775	82%	91%	97%	98%	2%
351-400 (19.4-22.2)	447	74%	84%	91%	95%	5%

NOTE: CGM readings are within 40-400 mg/dL (2.2-22.2 mmol/L), inclusive.

Tables 1-A and 1-B are categorized within CGM glucose ranges. When you see a CGM reading on your receiver, this table shows you how likely that reading matches your blood glucose level (measured by YSI in the study).

Agreement When CGM Reads "LOW" or "HIGH"

The System reports glucose concentrations between 40 and 400 mg/dL (2.2-22.2 mmol/L). When the System determines the glucose level is below 40 mg/dL (2.2 mmol/L), it displays "LOW" in the Receiver

Status Box. When the Dexcom G4 PLATINUM (Pediatric) System determines that the glucose level is above 400 mg/dL (22.2 mmol/L), it displays “HIGH” in the Receiver Status Box. Because the System does not display glucose values below 40 mg/dL (2.2 mmol/L) or above 400 mg/dL (22.2 mmol/L), the comparisons to the actual blood glucose concentrations (as determined by the YSI analyzer) when CGM is classified as “LOW” or “HIGH” are included separately in Tables 2-A (pediatric study) and 2-B (adult study). The table includes the numbers and the cumulative percentages when YSI values were less than certain glucose levels (for “LOW”), and when YSI values were greater than certain glucose levels (for “HIGH”).

Table 2-A. Number and Percentage of YSI Values When CGM Readings are ‘Low’ or ‘High’[8] (Pediatric Study)

		YSI mg/dL (mmol/L)					Total
CGM Readings	CGM-YSI pairs	< 55 (3.1)	< 60 (3.3)	< 70 (3.9)	< 80 (4.4)	≥ 80 (4.4)	
‘LOW’	n	0	0	0	0	13	13
	Cumulative Percent	0%	0%	0%	0%	100%	
		YSI mg/dL (mmol/L)					Total
CGM Readings	CGM-YSI pairs	> 340 (18.9)	> 320 (17.8)	> 280 (15.6)	> 240 (13.3)	≤ 240 (13.3)	
‘HIGH’	n	38	51	68	69	1	70
	Cumulative Percent	54%	73%	97%	99%	1%	

[8] In the pediatric clinical study, the subject’s glucose levels were not intentionally manipulated during this study, so there are fewer data samples in the low and high glucose ranges than in the adult clinical study.

Table 2-B. Number and Percentage of YSI Values When CGM Readings are 'Low' or 'High'[9] (Adult Study)

		YSI mg/dL (mmol/L)					Total
CGM Readings	CGM-YSI pairs	< 55 (3.1)	< 60 (3.3)	< 70 (3.9)	< 80 (4.4)	≥ 80 (4.4)	
'LOW'	n	64	82	122	142	13	155
	Cumulative Percent	41%	53%	79%	92%	8%	
		YSI mg/dL (mmol/L)					Total
CGM Readings	CGM-YSI pairs	> 340 (18.9)	> 320 (17.8)	> 280 (15.6)	> 240 (13.3)	≤ 240 (13.3)	
'HIGH'	n	189	220	238	246	2	248
	Cumulative Percent	76%	89%	96%	99%	1%	

Concurrence of System and Laboratory Reference

The percentage of concurring CGM readings and YSI reference values are included in Tables 3-A (pediatric study) and 3-B (adult study).

Tables 3-A (pediatric study) and 3-B (adult study) are categorized by ranges glucose values. This table describes, for each range of CGM glucose readings, what percentage of paired YSI values were in the same glucose range (shaded) or in glucose ranges above and below the paired CGM readings.

[9] In the pediatric clinical study, the subject's glucose levels were not intentionally manipulated during this study, so there are fewer data samples in the low and high glucose ranges than in the adult clinical study.

Table 3-A. Concurrence of CGM Readings and YSI Values (Pediatric Study)

	YSI mg/dL (mmol/L)											
Sensor mg/dL (mmol/L)	< 40 (2.2)	40-60 (2.2-3.3)	61-80 (3.4-4.4)	81-120 (4.5-6.7)	121-160 (6.7-8.9)	161-200 (8.9-11.1)	201-250 (11.1-13.9)	251-300 (13.9-16.7)	301-350 (16.7-19.4)	351-400 (19.4-22.2)	> 400 (>22.2)	Total
< 40 (2.2)	0%	0%	0%	54%	31%	15%	0%	0%	0%	0%	0%	13
40-60 (2.2-3.3)	0%	21%	58%	16%	5%	0%	0%	0%	0%	0%	0%	19
61-80 (3.4-4.4)	0%	21%	45%	30%	4%	0%	0%	0%	0%	0%	0%	76
81-120 (4.5-6.7)	0%	1%	20%	66%	12%	1%	0%	0%	0%	0%	0%	338
121-160 (6.7-8.9)	0%	0%	1%	36%	54%	7%	1%	0%	0%	0%	0%	511
161-200 (8.9-11.1)	0%	0%	0%	4%	40%	48%	6%	1%	0%	0%	0%	596
201- 250 (11.1- 13.9)	0%	0%	0%	1%	9%	44%	41%	5%	0%	0%	0%	658
251- 300 (13.9- 16.7)	0%	0%	0%	0%	2%	7%	50%	36%	3%	0%	2%	432
301- 350 (16.7- 19.4)	0%	0%	0%	0%	0%	2%	18%	59%	21%	0%	0%	206
351- 400 (19.4- 22.2)	0%	0%	0%	0%	0%	0%	3%	28%	50%	16%	2%	86
> 400 (> 22.2)	0%	0%	0%	0%	0%	0%	1%	14%	41%	36%	7%	70

Table 3-B. Concurrence of CGM Readings and YSI Values (Adult Study)

CGM mg/dL (mmol/L)	YSI mg/dL (mmol/L) Percent of matched pairs in each YSI glucose range for each Sensor glucose range											
	< 40 (<2.2)	40-60 (2.2-3.3)	61-80 (3.4-4.4)	81-120 (4.5-6.7)	121-160 (6.7-8.9)	161-200 (8.9-11.1)	201-250 (11.1-13.9)	251-300 (13.9-16.7)	301-350 (16.7-19.4)	351-400 (19.4-22.2)	> 400 (>22.2)	Number of Paired CGM-YSI
< 40 (< 2.2)	6%	48%	37%	7%	1%	0%	0%	0%	0%	0%	0%	155
40-60 (2.2-3.3)	4%	49%	36%	11%	1%	0%	0%	0%	0%	0%	0%	512
61-80 (3.4-4.4)	0%	22%	51%	24%	1%	0%	0%	0%	0%	0%	0%	781
81-120 (4.5-6.7)	0%	2%	17%	66%	13%	1%	0%	0%	0%	0%	0%	1706
121-160 (6.7-8.9)	0%	0%	1%	25%	60%	13%	2%	0%	0%	0%	0%	1492
161-200 (8.9-11.1)	0%	0%	0%	2%	28%	53%	16%	2%	0%	0%	0%	1240
201- 250 (11.1- 13.9)	0%	0%	0%	0%	3%	21%	51%	21%	3%	1%	0%	1181
251- 300 (13.9- 16.7)	0%	0%	0%	0%	0%	4%	19%	49%	24%	3%	0%	1018
301- 350 (16.7- 19.4)	0%	0%	0%	0%	0%	0%	3%	28%	51%	16%	1%	775
351- 400 (19.4- 22.2)	0%	0%	0%	0%	0%	0%	3%	10%	43%	38%	7%	447
> 400 (> 22.2)	0%	0%	0%	0%	0%	0%	1%	6%	21%	57%	15%	248

Accuracy Relative to YSI

Accuracy between matched pairs was also estimated by calculating the percent difference between the System reading and the YSI value. For example, if the YSI value is 100 mg/dL (5.6 mmol/L) and the System reading is 90 mg/dL (5.0 mmol/L), a 10% difference between the System and the YSI is reported. The System and YSI values were compared by pairing the System reading that occurred immediately after the YSI sample was collected.

In the example above, the System reading is less than the YSI value, so the percent difference reading is negative. The mean percent difference is the average of all positive and negative percent differences between the two devices; it tells you if the System reads higher or lower on average than the YSI within each glucose range.

Another estimate used to show the accuracy of the System is the absolute percent difference. The absolute percent difference tells you the percent difference or “distance” between the System and YSI values, but does not tell you whether the System is reading, on average, higher or lower than the YSI laboratory standard. The mean absolute percent difference is the average “distance” (regardless if positive or negative) between System readings and YSI values.

These accuracy measures in differences are based on 2922 paired glucose results and summarized in the following tables. Tables 4-A and Table 4-B represent the system difference within CGM glucose ranges from the pediatric and adults studies, respectively.

Table 4-A. System Difference to YSI within CGM Glucose Ranges (Pediatric Study)

CGM Glucose Ranges mg/dL (mmol/L)	Number of Paired CGM-YSI	Mean Percent Difference (%)	Median Percent Difference (%)	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)
Overall	2922	13.5	11.6	17.4	13.5
*40-60 (2.2-3.3)	19	-18.1 (-1.0)	-9.1 (-0.5)	19.2 (1.1)	9.1 (0.5)
*61-80 (3.4-4.4)	76	-3.7 (-0.2)	-2.3 (-0.1)	13.4 (0.7)	10.6 (0.6)
81-180 (4.5-10.0)	1155	11.9	9.7	17.0	13.0
181-300 (10.1-16.7)	1380	14.8	12.4	17.4	13.3
301-350 (16.7-19.4)	206	19.2	15.9	19.4	15.9
351-400 (19.4-22.2)	86	18.5	15.5	19.1	15.5

* For CGM ≤ 80 mg/dL (4.4 mmol/L), the differences in mg/dL (mmol/L) are included instead of percent differences (%).

NOTE: CGM readings are within 40 to 400 mg/dL (2.2- 22.2 mmol/L), inclusive.

Table 4-B. System Difference to YSI within CGM Glucose Ranges (Adult Study)

CGM Glucose Ranges mg/dL (mmol/L)	Number of paired CGM-YSI	Mean Percent Difference (%)	Median Percent Difference (%)	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)
Overall	9152	2.9	1.7	13.3	9.8
*40-60 (2.2-3.3)	512	-10.0 (-0.6)	-8.2 (-5.2)	13.5 (0.8)	9.7 (0.5)
*61-80 (3.4-4.4)	781	-2.4 (-0.1)	-0.4 (-0.0)	11.4 (0.6)	8.6 (0.5)
81-180 (4.5-10.0)	3853	4.8	3.0	13.8	9.8
181-300 (10.1-16.7)	2784	2.1	0.0	11.9	9.2
301-350 (16.7-19.4)	775	3.8	2.8	9.8	7.9
351-400 (19.4-22.2)	447	10.4	7.7	12.8	9.1

* For CGM ≤ 80 mg/dL (4.4 mmol/L), the differences in mg/dL (mmol/L) are included instead of percent differences (%).

NOTE: CGM readings are within 40 to 400 mg/dL (2.2-22.2 mmol/L), inclusive.

Low and High Glucose Alerts

The ability of the System to detect high and low glucose levels (concentrations) is assessed by comparing System results to YSI results at low and high blood glucose levels and determining if the alert may have sounded. The System and YSI readings were compared by pairing

the System reading that occurred immediately after the YSI reading was collected. There were 9555 paired System and YSI results evaluated. We suggest that you ask your doctor what alert settings would be best for you.

The Low Glucose Alert

Estimates of how well the adjustable Low Glucose Alert performs are presented in Tables 5-A through 5-C.[10] Table 5-A represents the alert evaluation within 15 minutes of the YSI reading for the pediatric study. It is a sub-set of the pediatric population—subjects age 6 to 17 years who had YSI measurements every 15 minutes. Table 5-B represents the alert evaluation within 15 minutes of the YSI reading for the adult study. Table 5-C represents the alert evaluation within 30 minutes of an SMBG reading for 2- to 5-year old subjects in the pediatric study.

Table 5-A. Hypoglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Pediatric Study, Ages 6-17)

Hypoglycemic Alert Level mg/dL (mmol/L)	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55 (3.1)	0%	100%	0%	100%
60 (3.3)	11%	89%	25%	75%
70 (3.9)	47%	53%	50%	50%
80 (4.4)	55%	45%	55%	45%
90 (5.0)	69%	31%	62%	38%
100 (5.6)	75%	25%	62%	38%

[10] In the pediatric clinical study, the subject's glucose levels were not intentionally manipulated, so there are fewer data samples in the low and high glucose ranges than in the adult clinical study.

Table 5-B. Hypoglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Adult Study)

Hypoglycemic Alert Level mg/dL (mmol/L)	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55 (3.1)	50%	50%	71%	29%
60 (3.3)	64%	36%	75%	25%
70 (3.9)	79%	21%	83%	17%
80 (4.4)	87%	13%	86%	14%
90 (5.0)	90%	10%	89%	11%

Table 5-C. Hypoglycemic Alert and Detection Rate Evaluation in Reference to SMBG 30 Minutes Before and After (Pediatric Study, Ages 2-5)

Hypoglycemic Alert Level mg/dL (mmol/L)	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55 (3.1)	3%	97%	57%	43%
60 (3.3)	11%	89%	62%	38%
70 (3.9)	29%	71%	77%	23%
80 (4.4)	35%	65%	85%	15%
90 (5.0)	51%	49%	89%	11%
100 (5.6)	64%	36%	91%	9%

Hypoglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the percent of time the device alarmed when the blood

glucose level was at or below the alert setting within 15 or 30 minutes before or after the device alarmed. The False Alert Rate is the percent of time the device alarmed when the blood glucose level was above the alert setting within 15 or 30 minutes before or after the device alarmed.

For example, if you set the Low Glucose Alert to 70 mg/dL (3.9 mmol/L) and your alarm sounds, how often can you expect your blood sugar to actually be low? If your alarm sounds, you can expect your blood sugar to be below 70 mg/dL (3.9 mmol/L) approximately 47% of the time (pediatric study) or 79% of the time (adult study) and not be below 70 mg/dL (3.9 mmol/L) approximately 53% of the time (pediatric study) or 21 % of the time (adult study) within the 15 minute period before or after your alarm sounds.

Hypoglycemia Detection Rate

The Detection Rate shows how often the device recognizes and alerts you to an episode of hypoglycemia or how often it misses such an event. The Hypoglycemia Detection Rate is the percent of time the blood glucose level was at or below the alert setting and device alarmed within 15 or 30 minutes before or after the blood glucose was at or below the alert settings. The Hypoglycemia Missed Detection Rate is the percent of time the blood glucose was at or below the alert setting, but the device did not alarm within 15 or 30 minutes before or after the blood glucose was at or below the alert setting.

For example, if you set the Low Glucose alert to 70 mg/dL (3.9 mmol/L), how often will your alarm alert you if your blood glucose goes below 70 mg/dL (3.9 mmol/L)? If your blood sugar goes below 70 mg/dL (3.9 mmol/L), you can expect your alarm to sound 50% of the time (pediatric study) or 83% of the time (adult study) and not to sound approximately 50% of the time (pediatric study) or 17% (adult study) of time within the 15 minute period before or after your blood sugar goes below 70 mg/dL (3.9 mmol/L).

The High Glucose Alert

Estimates of how well the adjustable High Glucose Alert performs are

presented in Tables 6-A through 6-C.[11] Table 6-A represents the alert evaluation within 15 minutes of the YSI reading for the pediatric study. It is a sub-set of the pediatric population—subjects age 6 to 17 years who had YSI measurements every 15 minutes. Table 6-B represents the alert evaluation within 15 minutes of the YSI reading for the adult study. Table 6-C represents the alert evaluation within 30 minutes of an SMBG reading for 2- to 5-year old subjects in the pediatric study.

Table 6-A. Hyperglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Pediatric Study, Ages 6 to 17 years)

Hyperglycemic Alert Level mg/dL (mmol/L)	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120 (6.7)	91%	9%	98%	2%
140 (7.8)	87%	13%	99%	1%
180 (10.0)	75%	25%	99%	1%
200 (11.1)	71%	29%	98%	2%
220 (12.2)	67%	33%	97%	3%
240 (13.3)	62%	38%	96%	4%
300 (16.7)	43%	57%	93%	7%

[11] In the pediatric clinical study, the subject's glucose levels were not intentionally manipulated, so there are fewer data samples in the low and high glucose ranges than in the adult clinical study.

Table 6-B. Hyperglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Adult Study)

Hyperglycemic Alert Level mg/dL (mmol/L)	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120 (6.7)	95%	5%	98%	2%
140 (7.8)	94%	6%	97%	3%
180 (10.0)	92%	8%	97%	3%
200 (11.1)	92%	8%	97%	3%
220 (12.2)	91%	9%	95%	5%
240 (13.3)	91%	9%	94%	6%
300 (16.7)	82%	18%	86%	14%

Table 6-C. Hyperglycemic Alert and Detection Rate Evaluation in Reference to SMBG 30 Minutes Before and After (Pediatric Study, Ages 2-5 years)

Hyperglycemic Alert Level mg/dL (mmol/L)	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120 (6.7)	92%	8%	98%	2%
140 (7.8)	90%	10%	98%	2%
180 (10.0)	87%	13%	96%	4%
200 (11.1)	85%	15%	96%	4%
220 (12.2)	81%	19%	95%	5%
240 (13.3)	80%	20%	95%	5%
300 (16.7)	71%	29%	90%	10%

Hyperglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the percent of time the device alarmed when the blood glucose level was at or above the alert setting within 15 or 30 minutes before or after the device alarmed. The False Alert Rate is the percent of time the device alarmed when the blood glucose level was below the alert setting within 15 or 30 minutes before or after the device alarmed.

For example, if you set the High Glucose alert to 200 mg/dL (11.1 mmol/L) and your alarm sounds, how often can you expect your blood sugar to actually be high? If your alarm sounds, you can expect your blood sugar to be at or above 200 mg/dL (11.1 mmol/L) approximately 71% of the time (pediatric study) or 92% of the time (adult study) and not be above 200 mg/dL (11.1 mmol/L) approximately 29% of the time (pediatric study) or 8% of the time (adult study) within the 15 minute period before or after your alarm sounds.

Hyperglycemia Detection Rate

The Detection Rate shows how often the device recognizes and alerts you to an episode of hyperglycemia or how often it misses such an event. The Hyperglycemia Detection Rate is the percent of time the blood glucose level was at or above the alert setting and the device alarmed within 15 or 30 minutes before or after the blood glucose was at or above the alert settings. The Hyperglycemia Missed Detection Rate is the percent of time the blood glucose was at or above the alert setting, but the device did not alarm within 15 or 30 minutes before or after the blood glucose was at or above the alert setting.

For example, if you set your High Glucose alert to 200 mg/dL (11.1 mmol/L), how often will your alarm alert you if your blood glucose goes at or above 200 mg/dL (11.1 mmol/L)? If your blood sugar goes above 200 mg/dL (11.1 mmol/L), you can expect your alarm to sound 98% of the time (pediatric study) or 97% of the time (adult study) and not to sound approximately 2% of the time (pediatric study) or 3% of time (adult study) within the 15 minute period before or after your blood sugar goes above 200 mg/dL (11.1 mmol/L).

Calibration Stability

The System must be calibrated every 12 hours. To demonstrate performance of the System over a 12-hour calibration period, sensors were evaluated to verify that performance remains consistent over the 12-hour calibration period. Systems were evaluated in 2-hour increments after calibration. Performance was estimated at each 2-hour interval and stratified by glucose concentrations by calculating the percentage of System readings within 15 mg/dL (0.9 mmol/L) or 15%, 20 mg/dL (1.1 mmol/L) or 20%, 30 mg/dL (1.7 mmol/L) or 30%, 40 mg/dL (2.2 mmol/L) or 40% and greater than 40 mg/dL (2.2 mmol/L) or 40% of the YSI values in Table 7.

Table 7. Percentage of System Readings within YSI Values with Data Stratified in 2-Hour Increments after Calibration (Pediatric Study)

Time from Calibration	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent within 40/40% YSI	Percent greater than 40/40% YSI
0-2 hours	648	65%	75%	87%	93%	7%
2-4 hours	649	51%	67%	86%	93%	7%
4-6 hours	630	51%	61%	80%	90%	10%
6-8 hours	409	52%	68%	85%	95%	5%
8-10 hours	296	53%	69%	84%	93%	7%
10-12 hours	253	58%	74%	89%	95%	5%
12-14 hours	37	32%	38%	65%	78%	22%

NOTE: CGM readings are within 40 to 400 mg/dL (2.2-22.2 mmol/L), inclusive.

Sensor Stability Relative to YSI

Sensors can be worn for up to 7 days. Performance was estimated by calculating the percentage of System readings within 15 mg/dL (0.9 mmol/L) or 15%, 20 mg/dL (1.1 mmol/L) or 20%, 30 mg/dL (1.7 mmol/L) or 30% , 40 mg/dL (2.2 mmol/L) or 40% and greater than 40 mg/dL (2.2 mmol/L) or 40% of the YSI values at the beginning (Day 1), middle (Day 4) and end (Day 7) of the System lifecycle. The average and median of the absolute percent differences are included in Table 8 showing consistent accuracy and sensor stability over the 7-day life of the sensor.

Table 8. Sensor Stability Relative to YSI (Accuracy over Time, Pediatric Study)

Day of Wear	Number of paired CGM-YSI	Mean Absolute Percent Differences (%)	Median Absolute Percent Differences (%)	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent within 40/40% YSI	Percent greater than 40/40% YSI
Day 1	1016	21.2	15.8	48%	61%	78%	85%	15%
Day 4	810	16.0	13.9	52%	66%	87%	97%	3%
Day 7	1096	15.1	11.3	63%	76%	89%	96%	4%

NOTE: CGM readings are within 40 to 400 mg/dL (2.2-22.2 mmol/L), inclusive.

Precision of System Readings

In the study, all subjects wore two Systems. This was to look at how similarly two Systems function on the same patient (sensor precision). Precision was evaluated by comparing the glucose readings from the two Systems worn on the same subject at the same time. Results showed that System readings from the two sensors generally agreed with each other within 10% (absolute percent difference) with a 7% coefficient of variation.

Sensor Life

Sensors may be worn for up to 7 days (168 hours). To estimate how long

a sensor will work over 7 days, 351 sensors were evaluated to determine how many days/hours of readings each sensor provided. Eighty-five percent (85%) of the sensors lasted until at least the start of Day 7 (145-168 hours).

Number of Readings Provided

The System is capable of providing a reading up to every 5 minutes, or up to 288 readings per day. For a variety of reasons, the System may not display a glucose reading and readings are "skipped." Table 9 estimates the number of readings you can expect to receive from the System over the entire 7-day period after calibration. Adjusted within each system wear-day, the System provided an average of 95% of all expected glucose readings as seen in Table 10.

Table 9. Number of Readings Provided by Each Sensor Over 7-Days (Pediatric Study)

% of Total Possible Readings Provided	Total Readings Provided (Min-Max)	% of Systems Providing that Number of Readings
0-25%	103-427	2.6%
26-50%	569-954	2.6%
51-75%	1006-1484	8.5%
76-100%	1518-1992	86.2%

Table 10. System Readings Within Wear Days (Pediatric Study)

Statistic	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	All Days (N = 108)
Mean	97%	96%	96%	95%	94%	94%	92%	95%
Median	99%	99%	99%	99%	99%	99%	98%	99%
STD	6%	10%	9%	12%	14%	14%	17%	12%

Agreement and Accuracy Relative to SMBG

During the study, agreement between the System and blood glucose values is also characterized using paired System and SMBG results (Tables 11-12). The System and SMBG values were compared by pairing the comparative SMBG value to a System glucose reading that occurred immediately after the SMBG was collected. These results characterize the performance patients expect during real-time use of the system in their daily diabetes management when comparing the system readings to their home blood glucose meter results.

Table 11. System Agreement to SMBG Within CGM Glucose Ranges (Pediatric Study)

CGM Glucose Ranges mg/dL (mmol/L)	Number of paired CGM-SMBG	Percent within 15/15% SMBG	Percent within 20/20% SMBG	Percent within 30/30% SMBG	Percent within 40/40% SMBG	Percent greater than 40/40% SMBG
Overall	16318	64%	76%	89%	95%	5%
40-60 (2.2-3.3)	487	44%	55%	68%	81%	19%
61-80 (3.4-4.4)	1340	59%	70%	85%	93%	7%
81-180 (4.5-10.0)	7084	62%	74%	90%	95%	5%
181-300 (10.1-16.7)	5627	69%	80%	90%	95%	5%
301-350 (16.7-19.4)	1176	65%	77%	90%	96%	4%
351-400 (19.4-22.2)	604	58%	72%	86%	94%	6%

NOTE: CGM readings are within 40 to 400 mg/dL (2.2-22.2 mmol/L), inclusive.

Table 11 is categorized within CGM glucose ranges. For readings less than or equal to 80 mg/dL (4.4 mmol/L) the absolute difference in mg/dL (mmol/L) between the two glucose results was calculated. For values greater than 80 mg/dL (4.4 mmol/L) the absolute percent difference (%) from the SMBG values was calculated. The percentages of total readings within 15 mg/dL (0.8 mmol/L) or 15%, 20 mg/dL (1.1 mmol/L) or 20%, 30 mg/dL (1.7 mmol/L) or 30%, 40 mg/dL (2.2 mmol/L) or 40% or greater than 40 mg/dL (2.2 mmol/L) or 40% were then calculated.

Table 12. System Difference to SMBG within CGM Glucose Ranges (Pediatric Study)

CGM Glucose Ranges mg/dL (mmol/L)	Number of Paired CGM-SMBG	Mean Percent Difference (%)	Median Percent Difference (%)	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)
Overall	16318	2.2	0.9	15.3	11.1
*40-60 (2.2-3.3)	487	-22.1 (-1.2)	-17.0 (-0.9)	23.9 (1.3)	18.0 (1.0)
*61-80 (3.4-4.4)	1340	-11.8 (-0.7)	-8.0 (-0.4)	17.0 (0.9)	11.0 (0.6)
81-180 (4.5-10.0)	7084	1.1	-1.0	15.4	11.4
181-300 (10.1-16.7)	5627	5.7	3.4	13.5	9.5
301-350 (16.7-19.4)	1176	9.6	7.2	14.2	10.4
351-400 (19.4-22.2)	604	12.7	10.2	16.1	11.9

* For CGM ≤ 80 mg/dL (4.4 mmol/L), the differences in mg/dL (mmol/L) are included instead of percent differences (%).

NOTE: CGM readings are within 40 to 400 mg/dL (2.2-22.2 mmol/L), inclusive.

Overall, the System reads, on average, 2.2% lower (Mean Percent Difference) than SMBG values and 15.3% absolute different (Mean Absolute Percent Difference) than the SMBG values. The Median Percent Difference shows that half of the time the System reads +0.9% or less than the SMBG values and the Median Absolute Percent Difference shows that half of the time the System reads about 11.1% or less different than SMBG values (Table 12).

Sensor Stability Relative to SMBG

Sensors can be worn for up to 7 days. Performance was estimated by calculating the percentage of system readings within various percentages of the SMBG values at each day of the sensor wear period (Table 13). The average and median of the absolute percent differences are included in the tables.

Table 13. Sensor Stability Relative to SMBG (Accuracy over Time, Pediatric Study)

Day of Wear	Number of paired CGM-SMBG	Mean Absolute Percent Differences (%)	Median Absolute Percent Differences (%)	Percent within 15/15% SMBG	Percent within 20/20% SMBG	Percent within 30/30% SMBG	Percent within 40/40% SMBG	Percent greater than 40/40% SMBG
Day 1	3216	18.8	14.2	53%	65%	81%	90%	10%
Day 2	2148	16.2	12.4	60%	74%	87%	94%	6%
Day 3	1977	15.2	11.0	63%	76%	89%	95%	5%
Day 4	2830	14.0	10.9	66%	79%	91%	96%	4%
Day 5	1768	15.4	10.7	67%	78%	90%	95%	5%
Day 6	1704	14.3	9.8	68%	79%	90%	96%	4%
Day 7	2675	12.4	9.2	72%	83%	94%	97%	3%

Adverse Events

No serious adverse events or device-related serious adverse events

occurred during the study. Mild skin irritation, such as erythema or edema, occurred in low frequency around the adhesive area. There were two examples of pain or discomfort during wear. No infection, bruising, or bleeding occurred at the sensor needle insertion area or the adhesive area.

14.2 PRODUCT SPECIFICATIONS

Sensor Product Specifications

Glucose Range	40 - 400 mg/dL
Sensor Life	Up to 7 days
Calibration	Commercially available blood glucose meter
Calibration Range	40 - 400 mg/dL
Storage Condition	Temperature: 36° F - 77° F Humidity: 15% - 85% RH
Sterilization	Sterile by radiation

Transmitter Product Specifications

Part Number	9438-01	9438-05
Dimensions (including sensor pod)	Length: 1.5 inches Width: 0.9 inches Thickness: 0.5 inches	Length: 1.5 inches Width: 0.9 inches Thickness: 0.4 inches
Weight (including sensor pod)	0.4 ounces	0.3 ounces
Power Supply	Silver oxide batteries (not replaceable)	
Operational Conditions	Temperature: 50° F - 108° F Humidity: 10% - 95% RH	

(continued on next page)

Transmitter Product Specifications (continued from page before)

Storage Conditions	Temperature: 32° F - 113° F Humidity: 10% - 95% RH
Operating Altitude	-500 to 12000 feet
Limited Warranty	6 months
Moisture Protection	IP28: temporary submersion
Protection Against Electrical Shock	Type BF applied part

Transmitter Performance Characteristics

Parameter	Performance Characteristics
TX/RX Frequencies	2.424 999 877 GHz 2.449 993 677 GHz 2.474 737 539 GHz 2.477 236 919 GHz
Bandwidth	334.7 kHz
Maximum Output Power	1.25 mW EIRP
Modulation	Minimum Shift Key
Data Rate	49.987 Kbits/Sec
Total Packet	224 bits
Transmit Duty Cycle	4.48 ms every 5 minutes at each of the four TX frequencies.
Data Detection Range	20 feet

The Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring System is safe for use on U.S. commercial airlines. The Dexcom G4 PLATINUM Transmitter is an M-PED with emission levels that meet RTCA/DO160, Section 21, Category M. Per FAA Advisory, Circular #91-21, 1B, dated 8/25/06, any M-PED that meets this standard in all modes may be used onboard the aircraft without any further testing by the operator. This device can withstand exposure to common electrostatic (ESD) and electromagnetic interference (EMI).

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The transmitter (P/N 9438-01 and P/N 9438-05) is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the transmitter should ensure that it is used in such an environment.

Transmitter Electromagnetic Immunity Specifications

Immunity Test	IEC 60601 Test Level	Transmitter Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) **IEC 61000-4-2**	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst **IEC 61000-4-4**	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable Battery operated	

(continued on next page)

Transmitter Electromagnetic Immunity Specifications
(continued from page before)

Immunity Test	IEC 60601 Test Level	Transmitter Compliance Level	Electromagnetic Environment Guidance
Surge **IEC 61000-4-5**	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable Battery operated	
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines **IEC 61000-4-11**	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Not applicable Battery operated	
Power Frequency **(50/60 Hz) Magnetic Field** **IEC 61000-4-8**	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: *U_T is the a.c. mains voltage prior to application of the test level.*

Receiver Product Specifications

Part Number	MT22608

(continued on next page)

Receiver Product Specifications (continued from page before)

Reading Frequency	Every 5 minutes
Dimensions	Length: 4.0 inches Width: 1.8 inches Thickness: 0.5 inches
Weight	2.4 ounces
Receiver Input	5V DC, 1A
Power Supply	MT21255
Communication Range	20 feet
Memory Storage	30 days of glucose data, 7 days of tech support data
Re-Chargeable Battery Use	3 days
Charging Time	3 hours wall outlet, 5 hours powered USB
Charging Temperature Condition	Temperature: 32° F - 104° F
Storage/Operating Conditions	Temperature: 32° F - 113° F Humidity: 10% - 95% RH
Operating Altitude	-500 to 12000 feet
Moisture Protection	IP22: vertically falling drops
Limited Warranty	1 year
Control Classification	Class II equipment

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The receiver (P/N MT22608) is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the receiver should ensure that it is used in such an environment.

Receiver Electromagnetic Immunity Specifications

Immunity Test	IEC 60601 Test Level	Receiver Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) **IEC 61000-4-2**	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst **IEC 61000-4-4**	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge **IEC 61000-4-5**	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical commercial or hospital environment.

(continued on next page)

Receiver Electromagnetic Immunity Specifications
(continued from page before)

Immunity Test	IEC 60601 Test Level	Receiver Compliance Level	Electromagnetic Environment Guidance
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines **IEC 61000-4-11** **IEC 60601-1-11**	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles 85% U_T (15% dip in U_T) for 5 sec < 5% U_T (> 95% dip in U_T) for 5 sec	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles 85% U_T (15% dip in U_T) for 5 sec < 5% U_T (> 95% dip in U_T) for 5 sec	
Power Frequency **(50/60 Hz) Magnetic Field** **IEC 61000-4-8**	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: *U_T is the a.c. mains voltage prior to application of the test level.*

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Dexcom G4 PLATINUM (Pediatric) System is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the Dexcom G4 PLATINUM (Pediatric) System should ensure that it is used in such an environment.

System Electromagnetic Immunity Specifications

Immunity Test	IEC 60601 Test Level	Receiver Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6 (Receiver only) **Radiated RF IEC 61000-4-3**	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 20 V/m 80 MHz to 2.4 GHz 10 V/m 2.4 GHz to 2.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the receiver, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance** $d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to

(continued on next page)

System Electromagnetic Immunity Specifications
(continued from page before)

Immunity Test	IEC 60601 Test Level	Receiver Compliance Level	Electromagnetic Environment Guidance
			the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with following symbol:

NOTE 1: *At 80 MHz and 800 MHz, the higher frequency range applies.*

NOTE 2: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Dexcom G4 PLATINUM (Pediatric) System is used exceeds the applicable RF compliance level above, the Dexcom G4 PLATINUM (Pediatric) System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Dexcom G4 PLATINUM (Pediatric) System.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Dexcom G4 PLATINUM (Pediatric) System is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the Dexcom G4 PLATINUM (Pediatric) System should ensure that it is used in such an environment.

Electromagnetic Emissions Specifications

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions **CISPR 11**	Group 1	The Dexcom G4 PLATINUM (Pediatric) System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

(continued on next page)

Electromagnetic Emissions Specifications (continued from page before)

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions **CISPR 11**	Class B	The Dexcom G4 PLATINUM (Pediatric) System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions **IEC 61000-3-2**	Not applicable	
Voltage Fluctuations/Flicker Emissions **IEC 61000-3-3**	Not applicable	

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Receiver

The receiver is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the receiver can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the receiver as recommended in the next table, according to the maximum output power of the communications equipment. Portable and mobile RF equipment include: baby monitors, *Bluetooth*® wireless headsets, wireless routers, microwave ovens, laptops with internal wi-fi adapters, GSM cell phones, RFID scanners and hand-held security metal detector often used by security screeners.

Minimum Recommended Distance Between Transmitter and Receiver

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\ P^{1/2}$	80 MHz to 800 MHz $d = 1.2\ P^{1/2}$	800 MHz to 2.5 GHz $d = 2.3\ P^{1/2}$
0.01 0.1 1 10 100	0.12 0.38 1.2 3.8 12	0.12 0.38 1.2 3.8 12	0.23 0.73 2.3 7.3 23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in feet can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture.

NOTE 1: *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

NOTE 2: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

USB Charging/Download Cable* Specifications

Dexcom P/N	MT20655
Input/Output	5V DC, 1A
Type	USB A to USB micro B
Length	3 feet

* The power supply/charger can be connected to the USB charging/download cable for charging using an AC power outlet.

Power Supply/Charger Specifications

Dexcom P/N	MT21255
Class	II
Input:	AC Input 100-240 Vac, 50/60Hz, 0.2A, 0.2A rms at 100Vac
DC Output:	5V DC, 1A (5.0 Watts)

14.3 FCC REQUIREMENTS

The transmitter covered by this user's guide has been certified under FCC ID: PH29433. The receiver has been certified under FCC ID: PH29495.

Although the transmitter and receiver have been approved by the Federal Communications Commission, there is no guarantee that they will not receive interference or that any particular transmission from the transmitter or receiver will be free from interference.

Compliance Statement (Part 15.19)

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:
1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Warning (Part 15.21)

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC Interference Statement (Part 15.105 (b))

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This portable transmitter with its antenna complies with FCC/IC RF exposure limits for general population/uncontrolled exposure.

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chapter fifteen

USER ASSISTANCE

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CHAPTER 15: USER ASSISTANCE

Dexcom Website:
www.dexcom.com

Dexcom Address:
6340 Sequence Drive
San Diego, CA 92121

TECHNICAL SUPPORT

For Dexcom product questions and troubleshooting issues[11].

Dexcom Technical Support Phone Numbers:
1.877.339.2664 or 1.858.200.0200
(24 hours, 7 days a week)

Dexcom Technical Support E-mail:
TechSupport@dexcom.com

Dexcom Technical Support Fax:
1.877.633.9266

SALES SUPPORT

For help with first-time orders, re-orders, tracking shipments, and locating a Dexcom representative in your area.

Dexcom Sales Support Phone Numbers:
1.877.339.2664 or 1.858.200.0200

Dexcom Sales Support E-mail:
CustomerService@dexcom.com

Dexcom Sales Support Fax:
1.877.633.9266

[11] Dexcom Technical Support does not offer medical advice.

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chapter sixteen

WARRANTY

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CHAPTER 16: WARRANTY

Dexcom G4 PLATINUM (Pediatric) System Limited Warranty

1. What is Covered and for How Long?

Dexcom, Inc. (“Dexcom”) provides a limited warranty to the original purchaser that the Dexcom G4 PLATINUM (Pediatric) Receiver with Share is free from defects in material and workmanship under normal use (“Limited Warranty”) for the period commencing upon the date of shipment and continuing for the following specified period of time after that date (“Warranty Period”):

Dexcom G4 PLATINUM (Pediatric) Receiver with Share:
1 Year

NOTE: If you received this receiver as a replacement for an in-warranty receiver, any remaining warranty on the original receiver shall transfer to this replacement receiver, and this warranty page shall be void.

2. What is Not Covered?

This Limited Warranty is conditioned upon proper use of the product by the purchaser. This Limited Warranty does not cover: (a) defects or damage resulting from accident, misuse, abuse, neglect, unusual physical, electrical or electromechanical stress, modification of any part of the product, or cosmetic damage; (b) equipment that has the ID number removed or made illegible; (c) all surfaces and other externally exposed parts that are scratched or damaged due to normal use; (d) malfunctions resulting from the use of the product in conjunction with accessories, products or ancillary or peripheral equipment not furnished or approved

by Dexcom; (e) defects or damage from improper testing, operation, maintenance, installation or adjustment; (f) installation, maintenance, and service of products; or (g) equipment that has been disassembled; or (h) water damage to the receiver (receiver is not water resistant, do not get the receiver wet at any time).

3. What are Dexcom's Obligations Under the Limited Warranty?

During the Warranty Period, Dexcom will replace, at Dexcom's sole option, without charge to purchaser, any defective Dexcom G4 PLATINUM (Pediatric) Receiver with Share. Purchaser must return the product to an authorized Dexcom Customer Support Department in an adequate container for shipping, accompanied by purchaser's sales receipt or comparable substitute proof of sale showing the date of purchase, the ID number of the product, and the seller's name and address. To obtain assistance on where to deliver the Dexcom G4 PLATINUM (Pediatric) Receiver with Share, call Dexcom Customer Support Department at **1.877.339.2664 or 1.858.200.0200**. Upon receipt, Dexcom will promptly replace the defective product. If Dexcom determines that any product is not covered by this Limited Warranty, purchaser must pay all shipping charges for the return of such product.

4. What are the Limits on Dexcom's Warranty and Liability Obligations?

THE LIMITED WARRANTY OF DEXCOM DESCRIBED ABOVE IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, EITHER IN

FACT OR BY OPERATION OF LAW, STATUTORY OR OTHERWISE, AND DEXCOM EXPRESSLY EXCLUDES AND DISCLAIMS ALL SUCH OTHER WARRANTIES, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT. EXCEPT TO THE EXTENT PROHIBITED BY APPLICABLE LAW, DEXCOM SHALL NOT BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, ARISING IN ANY WAY OUT OF THE SALE, USE, MISUSE OR INABILITY TO USE ANY DEXCOM G4 PLATINUM (PEDIATRIC) SYSTEM. THIS LIMITATION SHALL APPLY EVEN IF DEXCOM OR ITS AGENT HAS BEEN ADVISED OF SUCH DAMAGES AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF THIS LIMITED REMEDY. THIS LIMITED WARRANTY SHALL NOT EXTEND TO ANYONE OTHER THAN THE ORIGINAL PURCHASER OF THIS PRODUCT AND STATES PURCHASER'S EXCLUSIVE REMEDY.
IF ANY PORTION OF THIS LIMITED WARRANTY IS ILLEGAL OR UNENFORCEABLE BY REASON OF ANY LAW, SUCH PARTIAL ILLEGALITY OR ENFORCEABILITY SHALL NOT AFFECT THE ENFORCEABILITY OF THE REMAINDER OF THIS LIMITED WARRANTY WHICH PURCHASER ACKNOWLEDGES IS AND WILL ALWAYS BE CONSTRUED TO BE LIMITED BY ITS TERMS OR AS LIMITED AS THE LAW PERMITS.

Dexcom G4 PLATINUM Transmitter Limited Warranty

1. What Is Covered And For How Long?

Dexcom, Inc. (“Dexcom”) provides a limited warranty to the original purchaser that the Dexcom G4 PLATINUM Transmitter is free from defects in material and workmanship under normal use (“Limited Warranty”) for the period commencing upon the date of shipment and continuing for the following specified period of time after that date (“Warranty Period”):

Dexcom G4 PLATINUM Transmitter: 6 Months

NOTE: If you received this transmitter as a replacement for an in-warranty transmitter, any remaining warranty on the original transmitter shall transfer to this replacement transmitter, and this warranty page shall be void.

2. What Is Not Covered?

This Limited Warranty is conditioned upon proper use of the product by the purchaser. This Limited Warranty does not cover: (a) defects or damage resulting from accident, misuse, abuse, neglect, unusual physical, electrical or electromechanical stress, modification of any part of the product, or cosmetic damage; (b) equipment that has the ID number removed or made illegible; (c) all surfaces and other externally exposed parts that are scratched or damaged due to normal use; (d) malfunctions resulting from the use of the product in conjunction with accessories, product or ancillary or peripheral equipment not furnished or approved by Dexcom; (e) defects or damage from improper testing, operation, maintenance, installation or adjustment; (f) installation, maintenance, and service of products; (g) equipment that has been disassembled, or (h) water damage to the transmitter beyond the specifications listed in the

Dexcom G4 PLATINUM (Pediatric) CGM System User's Guide, a copy of which was included with your Dexcom G4 PLATINUM (Pediatric) CGM System and may be found at www.dexcom.com.

3. What Are Dexcom's Obligations Under The Limited Warranty?

During the Warranty Period, Dexcom will replace, at Dexcom's sole option, without charge to purchaser, any defective Dexcom G4 PLATINUM Transmitter. Purchaser must return the product to an authorized Dexcom Customer Support Department in an adequate container for shipping, accompanied by purchaser's sales receipt or comparable substitute proof of sale showing the date of purchase, the ID number of the product, and the seller's name and address. To obtain assistance on where to deliver the Dexcom G4 PLATINUM Transmitter, contact Dexcom Customer Support Department at **1.877.339.2664 or 1.858.200.0200**. Upon receipt, Dexcom will promptly replace the defective product. If Dexcom determines that any product is not covered by this Limited Warranty, purchaser must pay all shipping charges for the return of such product.

4. What Are The Limits on Dexcom's Warranty And Liability Obligations?

THE LIMITED WARRANTY OF DEXCOM DESCRIBED ABOVE IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, STATUTORY OR OTHERWISE, AND DEXCOM EXPRESSLY EXCLUDES AND DISCLAIMS ALL SUCH OTHER WARRANTIES,

INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT. EXCEPT TO THE EXTENT PROHIBITED BY APPLICABLE LAW, DEXCOM SHALL NOT BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, ARISING IN ANY WAY OUT OF THE SALE, USE, MISUSE OR INABILITY TO USE ANY DEXCOM G4 PLATINUM (PEDIATRIC) CGM SYSTEM. THIS LIMITATION SHALL APPLY EVEN IF DEXCOM OR ITS AGENT HAS BEEN ADVISED OF SUCH DAMAGES AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF THIS LIMITED REMEDY. THIS LIMITED WARRANTY SHALL NOT EXTEND TO ANYONE OTHER THAN THE ORIGINAL PURCHASER OF THIS PRODUCT AND STATE PURCHASER'S EXCLUSIVE REMEDY.
IF ANY PORTION OF THIS LIMITED WARRANTY IS ILLEGAL OR UNENFORCEABLE BY REASON OF ANY LAW, SUCH PARTIAL ILLEGALITY OR ENFORCEABILITY SHALL NOT AFFECT THE ENFORCEABILITY OF THE REMAINDER OF THIS LIMITED WARRANTY WHICH PURCHASER ACKNOWLEDGES IS AND WILL ALWAYS BE CONSTRUED TO BE LIMITED BY ITS TERMS OR AS LIMITED AS THE LAW PERMITS.

chapter seventeen

TRAVEL INFORMATION

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CHAPTER 17: TRAVEL INFORMATION

It is safe for you to go through the metal detector or be “handwanded” while wearing your Dexcom sensor and transmitter. If you’re concerned or uncomfortable about going through the walk-through metal detector, the Transportation Security Administration (TSA) states that you should notify the Security Office that you’re wearing a continuous glucose monitor and would like a full-body pat-down and a visual inspection of your Dexcom sensor and transmitter instead. Advise the Security Office that the sensor cannot be removed because it is inserted under the skin.

Instead of putting your Dexcom G4 PLATINUM (Pediatric) System through the x-ray, request that the TSA officer perform a visual inspection. This must be requested before the screening process begins. Your Dexcom G4 PLATINUM (Pediatric) System components that are not attached to your body (e.g., receiver, extra sensors) should be ready in a separate bag when you approach the Security Officer. For other medical supplies, such as medications, meters and strips, check the manufacturer’s instructions or the TSA website.

You may keep the receiver on before take-off, while in flight and after landing. The Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring System is safe for use on U.S. commercial airlines. The Dexcom G4 PLATINUM Transmitter is an M-PED with emission levels that meet RTCA/DO160, Section 21, Category M. Per FAA Advisory, Circular #91-21, 1B, dated 8/25/06. Any M-PED that meets this standard in all modes may be used onboard the aircraft without any further testing by the operator. This device can withstand exposure to common electrostatic (ESD) and electromagnetic interference (EMI).

Visit the TSA’s website if you have any questions or concerns.

www.tsa.gov

E-mail: TSA-ContactCenter@dhs.gov

Phone: Call 1.866.289.9673

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chapter eighteen

APPENDIX

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CHAPTER 18: APPENDIX

APPENDIX I: RECEIVER ALERTS, ALARM AND PROMPTS

The following tables describe the alarm, alerts and prompts and how the receiver notifies you.

Prompt - Shows on screen only. Silent, no vibrate or beep.
Alert - Notifies with vibrate and beep depending on your profile settings.
Alarm - Low 55 - Notifies with vibrate and beep. Cannot be changed.

Receiver Alerts, Alarm and Prompts

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
	Low glucose alarm	Your most recent sensor glucose reading is at or below 55 mg/dL.	Vibrates 4 times and then vibrates/beeps 4 times every 5 minutes until confirmed or your glucose value goes above 55 mg/dL.	Yes, every 30 minutes after each confirmation until your blood glucose value comes back into range.

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Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
	High glucose alert	Your most recent sensor glucose reading is at or above the high alert setting.	Vibrates 2 times and then vibrates/beeps 2 times every 5 minutes until confirmed or your glucose value drops below the alert level.	No, unless you have turned on the high snooze feature. See Chapter 9, Section 9.2, Advanced Alerts.
	Low glucose alert	Your most recent sensor glucose reading is at or below the low alert setting.	Vibrates 3 times and then vibrates/beeps 3 times every 5 minutes until confirmed or your glucose value goes above the alert level.	No, unless you have turned on the low snooze feature. See Chapter 9, Section 9.2, Advanced Alerts.

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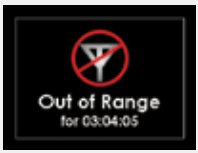
Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
	Low battery alert	The receiver battery is low. Charge your receiver as soon as possible when you see this alert.	Vibrates 1 time at 20% battery capacity left.	Yes, at 10% battery capacity left.
	Out of Range alert	The transmitter and receiver are not communicating and you will not receive sensor glucose readings.	Vibrates 1 time and then vibrates/beeps every 5 minutes until the receiver and transmitter are back in range.	No, unless you have turned on the out of range alert.

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Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
	Glucose reading error prompt	The sensor is sending sensor glucose readings that the receiver does not understand. You will not receive sensor glucose readings.	Symbol in status area only.	N/A

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Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
	Wait prompt	The receiver has detected a potential problem with the sensor signal. You should wait about 30 minutes for more prompts. Do not enter any blood glucose values during this time. You will not receive sensor glucose readings.	Symbol in status area only.	N/A

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Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
	Wait 15 minutes calibration error alert	The sensor cannot calibrate. Wait 15 minutes then enter 1 more blood glucose value. Wait 15 more minutes. If error screen still appears enter 1 more blood glucose value. Wait 15 minutes. If no sensor glucose readings appear on the receiver, the sensor needs to be replaced.	Vibrates 1 time and then vibrates/beeps every 5 minutes until confirmed.	No

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Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
	Wait 1 hour calibration error alert	The sensor cannot calibrate. Wait a minimum of 1 hour then enter 1 more blood glucose value for calibration. If no sensor glucose readings appear on the receiver, the sensor needs to be replaced.	Vibrates 1 time and then vibrates/beeps every 5 minutes until confirmed.	No
	12-hour calibration prompt	The receiver needs a blood glucose value entered to calibrate.	Prompt screen only.	Yes, every 15 minutes.

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Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
	Calibration prompt	The receiver needs a blood glucose value entered to calibrate. Sensor glucose readings will not be displayed at this time.	Vibrates 1 time and then vibrates/beeps every 5 minutes until confirmed.	Yes, every 15 minutes.
	Startup calibration prompt	The receiver needs 2 blood glucose values entered to calibrate.	Vibrates 1 time and then vibrates/beeps every 5 minutes until confirmed.	Yes, every 15 minutes.
	Additional startup calibration prompt	The receiver needs 1 additional blood glucose value to complete startup calibration.	Vibrates 1 time and then vibrates/beeps every 5 minutes until confirmed.	Yes, every 15 minutes.

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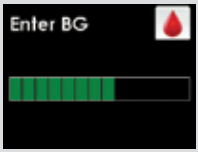
Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
	Enter BG processing screen prompt	The receiver is processing the blood glucose value you entered.	Prompt screen only.	N/A
	Rise alert	Your glucose levels are rising at 2 mg/dL per minute or more.	Vibrates 2 times and then vibrates/beeps 2 times every 5 minutes or until confirmed (2 repeats max).	No
	Rapid rise alert	Your glucose levels are rising fast at 3 mg/dL per minute or more.	Vibrates 2 times and then vibrates/beeps 2 times every 5 minutes or until confirmed (2 repeats max).	No

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Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
	Fall alert	Your glucose levels are falling at 2 mg/dL per minute or more.	Vibrates 3 times and then vibrates/beeps 3 times every 5 minutes or until confirmed (2 repeats max).	No
	Rapid fall alert	Your glucose levels are falling fast at 3 mg/dL per minute or more.	Vibrates 3 times and then vibrates/beeps 3 times every 5 minutes or until confirmed (2 repeats max).	No
	6-hour sensor expiration prompt	Your sensor session will end in 6 hours.	Prompt screen only.	N/A
	2-hour sensor expiration alert	Your sensor session will end in 2 hours.	Prompt screen only.	No

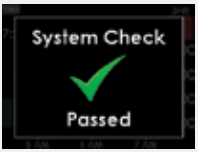
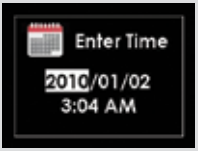
(continued on next page)

Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
	30-minute sensor expiration alert	Your sensor session will end in 30 minutes.	Vibrates 1 time and then vibrates/beeps every 5 minutes (2 repeats max).	No
	End of session sensor expiration alert	Your sensor session has ended.	Vibrates 1 time and then vibrates/beeps every 5 minutes (2 repeats max).	No
	Sensor failed alert	The sensor is not working properly.	Vibrates 1 time and then vibrates/beeps every 5 minutes (2 repeats max).	Yes, 2 re-alerts in the next 10 minutes for 30 minutes.

(continued on next page)

Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
	Receiver error code alert	Your receiver is not working properly. Record the error code and call Dexcom Technical Support.	Vibrates 1 time (4 seconds) + 4 beeps.	No
	System recovery check alert	There was a system error and the receiver fixed it.	Vibrates 1 time and then vibrates/beeps every 5 minutes until confirmed.	No
	Set time/date prompt	Backup battery has drained, time/date need to be reset.	Vibrates 1 time.	No
	Transmitter low battery alert	Transmitter battery is low. Replace the transmitter as soon as possible.	Vibrates 1 time and then vibrates/beeps every 5 minutes (2 repeats max).	Yes, once a day.

(continued on next page)

Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
	Transmitter failed alert	The transmitter has failed. Replace the transmitter immediately.	Vibrates 1 time and then vibrates/beeps every 5 minutes (2 repeats max).	No
	Share unsuccessful pairing prompt	Your receiver is having trouble connecting with your iPhone or iPod touch via *Bluetooth*.	Prompt screen only.	No

Important alerts that can be checked by the user:

- **Out of range alert -** You can test this alert by moving the receiver more than 20 feet away for 30 minutes or more.
- **30-minute sensor expiration alert -** You will see this alert in the normal course of using a sensor for seven days.
- **0-hour sensor expiration alert -** You will see this alert in the normal course of using a sensor for seven days.

Other alerts and alarms cannot be safely checked by the user.

APPENDIX II: INDEX

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APPENDIX III: SYMBOLS USED IN LABELING

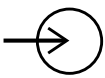
The following symbols may be found on the sensor, transmitter, and receiver package labels. These symbols tell you about the proper and safe use of the Dexcom G4 PLATINUM (Pediatric) CGM System. Some of these symbols may not have meaning in your region, and are listed for informational purposes only. This table shows what each symbol means.

Symbols

	"Use By" Date	LOT	Lot Number
	Caution	REF	Part Number, Catalog Number
	Date of Manufacture	STERILE R	Sterile by Radiation
	Do Not Reuse		Two-Sided Temperature Limits
SN	Serial Number	IP28	Temporary submersion
	Class II Equipment	IP22	Vertically falling drops
~	Alternating Current	⎓	Direct Current
	Type BF Applied Part		Follow Operating Instructions

(continued on next page)

Symbols (continued from page before)

	Manufacturer		Authorized Representative in the European Community
	Two-Sided Humidity Limitation		Non-ionizing Radiation
	European Union WEEE Directive 2006-66-EC		Marking Certifies that the device meets the European Council Directive 93/42/EEC
	Electrical Equipment Designed Primarily for Indoor Use		Do Not Use if Package is Damaged
	Input	**SB**	Ship By Date
	Keep Dry	**Rx Only**	Prescription Required
	Bluetooth		MR Unsafe

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6340 Sequence Drive
San Diego, CA 92121 USA
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1.877.339.2664
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